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# "The Silver Sheet"®

MEDICAL DEVICE QUALITY CONTROL

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## THE NEWS THIS ISSUE

- **RECALLS SOARED TO THEIR HIGHEST POINT EVER IN 2008,** with companies recalling a total of 845 devices. Many of the recalls were related to software problems and tainted heparin. "The goal is to try and decrease those recalls," says Tim Ulatowski, director of CDRH's Office of Compliance. "So we're trying to push that number down through effective enforcement actions and industry training." There is good news, however: The number of Class I recalls fell from 23 in 2007 to only 17 in 2008 – industry's best Class I showing since 2003. Also, the recall manager for a Virginia hospital chain tells what companies should do to make their recall letters clearer and easier to comply with. "We get some recall letters and we truly don't know what to do with them," Bea Haupt says ..... **Below**
- **COMPLETE TABLE OF RECALLS FROM 2008** includes 17 Class I (2%), 726 Class II (86%) and 107 Class III (12%) medical device events ..... **12**
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## Problems Related To Software, Heparin Help Push Recalls To All-Time High

*Also, FDA And Industry Experts Give Tips For Composing Recall Letters*

The number of recalled medical devices skyrocketed last year to its highest point ever, spurred on by a large volume of Class II recalls related to product software and devices containing tainted heparin.

"Software is an area where we're seeing ... an uptick in the reason for problems with products," says Tim Ulatowski, director of CDRH's Office of Compliance. "As the products become more intricate and software-driven, we want to make sure we're ahead of the problems."

Manufacturers initiated a total of 845 device recalls in calendar year 2008, up 43 percent from 2007, when 591 recalls were logged. (*See chart, p. 3.*)

For its 2008 figures, "The Silver Sheet" counted recalls issued during the calendar year, while FDA tallies recalls according to fiscal year (Oct. 1-Sept. 30). The differences between those two counting methods are typically negligible; the agency counted 831 total recalls in FY 2008 and 664 in FY 2007.

"The goal is to try and decrease those recalls," Ulatowski says. "So we're trying to push that number down through effective enforcement actions and industry training."

There were 726 recalls designated as Class II last year, accounting for the bulk of the recalls. That is a 49 percent increase over 2007, when 487 Class II recalls were reported.

According to a "Silver Sheet" analysis, software problems accounted for 71 of the Class II recalls.

Software anomalies were noted as the reason for one Class I recall: Physio-Control's ***LifePak CR Plus*** automated external defibrillator was configured with incorrect software.

Class I is FDA's most serious recall category, reserved for situations where the agency believes patients face a reasonable probability of serious injury or death from use of the defective products.

Nine Class III recalls also were attributed to software problems.

"We're looking at software recalls in more detail. Software is subject to [an agency] analysis that's going on," Ulatowski says.

FDA is trying to determine "software's contribution to the total recall package," he notes. "And then as we drill down, what are the specific areas that created the software recalls? We're trying not to be superficial. We're trying to get down to the exact problem areas that generated the problems so we can target solutions."

Ulatowski also says there is a continuing need to train FDA investigators on the intricacies of devices that contain software.

FDA Senior Recall Coordinator Melvin Szymanski blames poor software development for the spike.

"Software development is being done quickly in the beginning, and then firms are marketing the product before fixing the software glitches that should be tested-out during product development," he says.

Many of the software problems could be avoided if companies performed proper real-world testing, Szymanski told "The Silver Sheet."

"Let's say it's a device used in a hospital. You better have a nurse come and test that device for you, because he or she is going to show you shortcuts that your labeling doesn't take into account," he says. "And then you need to figure out how to prevent that from happening."

FDA also is warning manufacturers not to put off recalling bad software while they wait for appropriate fixes to be developed.

"A lot of time in the device industry I'll hear, 'You know Mike, we'll recall that about six years from now when we get the software update,'" says Mike Verdi, also a senior recall coordinator for FDA. "No, no, no. Recall it now."

### Software Problematic For Diagnostics, Too

FDA's Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD) also is trying to determine the best way to curb software recalls tied to in vitro diagnostic (IVD) products.

"We're trying to figure out how much we should be concerned about software recalls," says Ian Pilcher, an OIVD consumer safety officer.

"Software is pretty complicated when it's put in these instruments," he says. "So what we're trying to get a handle on is, how we should review this stuff and how we should look for problems. It's kind of a newer field for us, and we don't see all the [software] code. We're more familiar with looking at testing data and clinical data – that sort of thing – but software is a little bit of a black box."

Pilcher told "The Silver Sheet" that problems with software are the third most-common IVD recall issue.

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F-D-C REPORTS, INC.
5635 FISHERS LANE, Suite 6000
ROCKVILLE, MD 20852
PHONE 240-221-4500
FAX 240-221-4400

Customer Service:
1-800-332-2181 or 1-908-547-2159 Fax 908-547-2165
E-mail: fdcwindhover.custcare@elsevier.com

AN ELSEVIER COMPANY

*Executive Editor:*
**Mary Houghton**
240-221-4410 m.houghton@elsevier.com

*Managing Editor:*
**Shawn M. Schmitt**
240-221-4419 sm.schmitt@elsevier.com

*Composition:*
**Ting Yang**

*Production:*
**Phil Simms**

*Corporate Sales:*
**Tom DePaul**
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"The devices are becoming more and more complex," he says. "Although we don't regulate them in the pre-market sense, you have things like lab information systems, hospital information systems, and things like that, so we also get some recalls with those."

Further, "glucose meters are starting to do more things in terms of tracking and downloading data, so it's just kind of a broader field of devices that are coming under scrutiny," Pilcher notes.

Because the review of IVD software is relatively new to OIVD, the office is relying on the honesty of manufacturers when it comes to recalls.

"One of the trickier things is, the only information we get from the firms is that it's a software recall," Pilcher says.

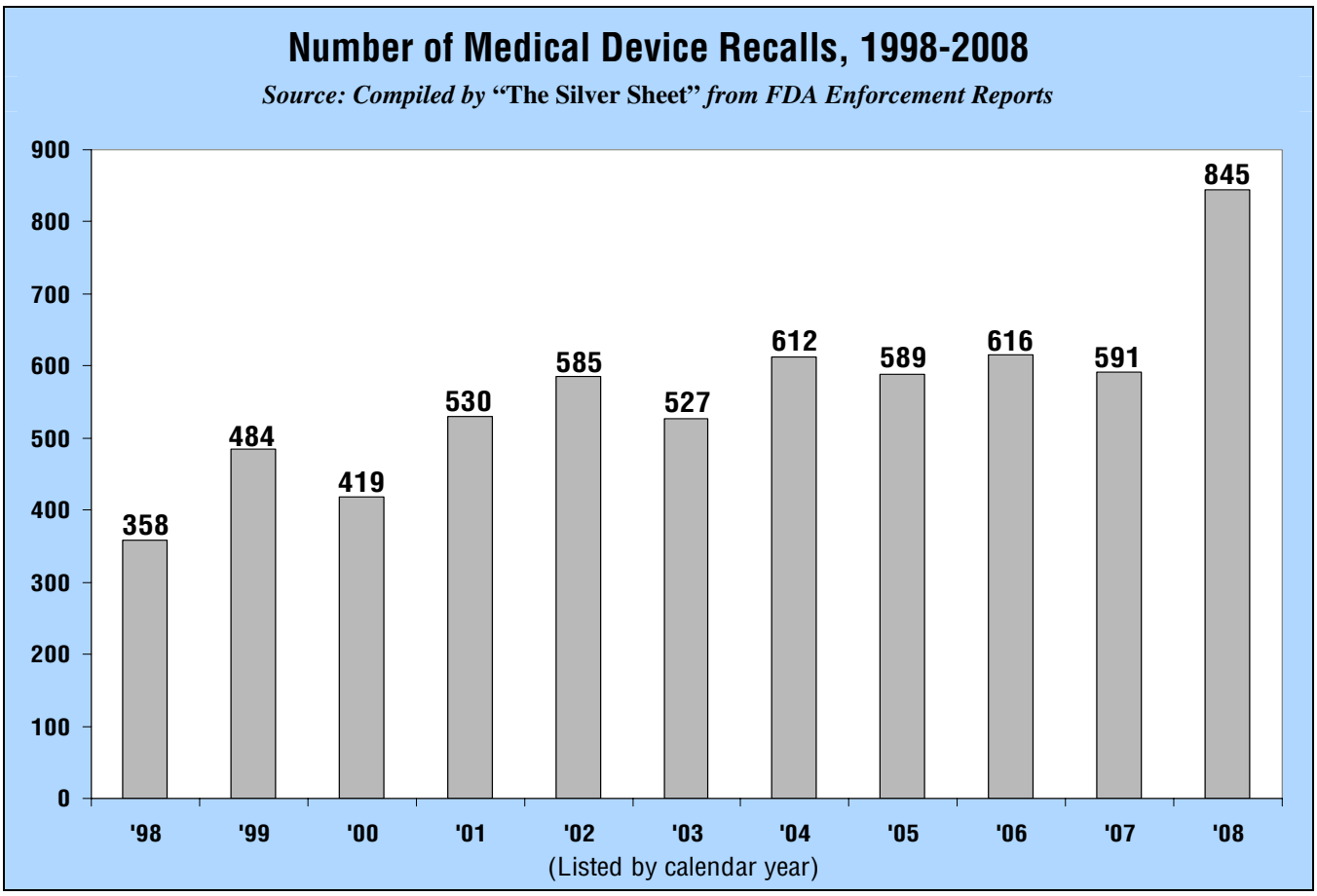
"It's a little more difficult for us to get to the root cause and to ask the right questions. Whereas, once you see clinical data or analytical testing data, it's a lot easier for us to get to the basic problem that hasn't been fixed," he says. "But with software, we're relying an awful lot on the firms to just be up front with us and honest, because we don't see those results so easily."

The software review process is difficult for OIVD, Pilcher says, because there is an overwhelming amount of software in some IVDs.

"You can imagine the amount of software for some of these complex analyzers. And we don't look at the code; we don't thoroughly review it," he says. "For most IVDs ... we're reviewing their verification and validation, and design controls and specifications – that's it."

Pilcher says he isn't aware of an effort to hire software engineers or developers for OIVD. Rather, the office is working with FDA's Office of Science and Engineering Laboratories (OSEL) to determine the best approach for reviewing and weeding out bad IVD software.

"We're looking more in terms of what tools are out there – software analysis and software forensic tools – that we could use," he says. "With the volume of devices we get in, I think viewing the actual code would be extremely difficult and time-consuming. So while I think there's becoming more and more of an emphasis on it – and doing it correctly – I don't think there's any move to actually look at the [software] code" during the pre-market phase.



### Tainted Heparin Also Cause Of Class II Recalls

Meanwhile, devices containing tainted heparin were the cause of 11 Class II recalls by firms such as Medtronic, Baxter, Covidien and Beckman Coulter, the "Silver Sheet" analysis found.

"You had only a couple of [firms] in the country that deal with bringing in bulk heparin, and they go into all your products," FDA's Szymanski says. "That's a good example of one component going bad and causing a whole lot of recalls."

Patient deaths and adverse events have been linked to heparin manufactured in China that was contaminated with oversulfated chondroitin sulfate (OSCS), which mimics heparin's qualities. FDA officials say OSCS is much cheaper to produce ("The Silver Sheet" May 2008).

These types of situations happen because the "United States manufacturer ... will manufacture a product as cheaply as it can because it can sell it at a slightly lower price than its competitor, but still make a lot of money to pay everybody in the company, give bonuses and stock options, and also pay the stockholders a decent dividend," Szymanski says.

"If you're going to make a catheter, and there are several catheters that do the same thing, if you can put it on the market at a lower price, you're going to get more sales," he adds.

To help spot troubling trends more quickly, the agency opened several new overseas offices under its import safety initiative ("The Silver Sheet" October 2008).

Three offices opened in China last November. More recently, FDA offices were opened in Costa Rica, Brussels, and New Delhi, India. Locations in Mumbai, India, and the Middle East also are planned.

"FDA has recognized that it no longer regulates only what's happening in the United States," Szymanski says. "We have to regulate the world, because a large percentage of [devices and components] in the United States isn't even produced here.

"A large percentage of the products are being recalled because of the components, sub-components or ingredients, or because they're manufactured outside the United States," he continues. "What we're hoping is, by having [FDA staff] in these cities, we're going to have ears, and we're going to get to know our foreign regulatory counterparts on a far better basis so we can hear intelligence."

***"A large percentage of the products are being recalled because ... they're manufactured outside the United States," FDA's Szymanski says.***

For example, if a particular device or component manufactured in China is having problems, "we're going to hear about that sooner, hopefully in one of our China offices, than we would sitting here in the United States, trying to pick it up through the Internet or some other outlet," Szymanski says.

### Class III Recalls Rise, But Class I's Fall

There also was a marked upsurge in the less-serious Class III device recalls last year. There were 107 Class III's in 2008, a 25 percent increase from 2007, when 81 recalls were given that designation.

However, there is some good news: The number of Class I recalls fell from 23 in 2007 to 17 in 2008. (By FDA's fiscal-year-based count, there were 14 Class I events in FY 2008.)

That's industry's best Class I showing since 2003, when only nine recalls were given that designation. (*See chart, p. 6.*)

Medtronic led the pack with three Class I recalls related to its ***SynchroMed*** and ***IsoMed*** infusion pumps, as well as its ***Indura*** intrathecal catheter. (*See chart, p. 7.*)

## FDA Recall Classifications

**Class I:** There is a reasonable probability that the use of, or exposure to, a violative product will cause serious adverse health consequences or death.

**Class II:** Use of, or exposure to, a violative product may cause temporary or medically reversible adverse health consequences, or the probability of serious adverse health consequences is remote.

**Class III:** Use of, or exposure to, a violative product is not likely to cause adverse health consequences.

Other notable Class I recalls last year included Cardinal Health's ***Alaris*** infusion pump, Covidien's ***ReliOn*** insulin syringes and Boston Scientific's ***NexStent*** carotid stents.

"On Class I's, we are following up. Every Class I deserves a follow-up inspection," FDA's Ulatowski told "The Silver Sheet."

"We're addressing each of these recalls as they're reported, and each of them requires a lot of attention on our part," he says. "It's also a workload for the districts, and we won't close out [Class I recalls] until we're sure that things are being handled OK on their end."

***Siemens, Stryker, General Electric, Abbott, Medtronic and Biomet initiated the most device recalls in 2008.***

### FDA: Failure Of Firms To Adequately Validate Plays Large Role In Total Number Of Recalls

FDA's Ulatowski says CDRH had to increase staff and work overtime to address the enormous number of recalls initiated in 2008.

"We have a Recall Branch, and I've completed staffing that entire branch and assigned additional staff as necessary to get the recall reports closed out and attended to in order to get the recall classifications done," he says.

Ulatowski recently appointed Rita Hoffman to lead the Recall Branch, which now has six employees "who interface with the districts and with our other operating divisions to get their work done."

Further, the districts "need appropriate resources to do the job that needs to be done, so they need to be supported fully as well," he says. "I don't want to leave an impression with 'Silver Sheet' readers that we just push paper and make entries in computers.

"The whole recall program is one important set of signals that are assessed to see where problems are at, and we use recall data in determining whom to inspect," Ulatowski continues. "We also examine recalls globally in terms of product lines to try and get a picture of what's happening. So these are all very important things that are more than just processing recalls."

FDA's Szymanski speculates that most recalls occur because manufacturers aren't properly validating their processes and products.

"The firm is supposed to have a validated system, which means it makes the product the same way every single time. Nothing varies," he says. However, "if something varies, it should get caught before it leaves the door."

Szymanski points out that a problem with supplied components often is the cause of recalls.

"Let's say you're depending on a battery, and the person supplying you the battery has battery problems and they supply to you without realizing that they have battery problems," he explains. "It results in your device being recalled because of the battery issue, which was the really the battery component manufacturer's problem.

"So it's a check-and-balance system, and the question becomes, 'How robust is your check-and-balance system?'" Szymanski adds. "The manufacturer of the product is supposed to inspect the component manufacturers that go into that product, and the manufacturer should require really strict, hard validation – and a robust validation – to make sure that components are not bad, or that bad parts or components do not get out to them for assembly into their devices.

"And then, of course, they're supposed to have robust testing to validate the product coming into them as components. So it's a whole series of checks and balances, and somewhere those checks and balances are falling down."

OIVD's Pilcher agrees that poor validation activities are a reason for some in vitro diagnostic recalls.

"That's always a potential problem," he says. "I also do pre-market reviews, so I work on both sides of the coin, and I find out sometimes from a firm's regulatory staff that their marketing department is really pushing a device.

"Marketing really wants a certain claim, or they really want the device to be out by a certain date," Pilcher notes. "We realize that the firms are coming under pressure that way. So they may be rushing things out without doing what we would consider the appropriate validation."

### Large-Firm Acquisitions May Affect Volume Of Recalls

Last year's large volume of recalls also may be due to a ripple effect from a number of large companies gobbling up smaller ones, FDA's Szymanski says.

"There used to be a lot of independent companies, and they've been bought up by these super-companies," he says. "So when the super-companies start saying, 'We're going to save a lot of money because we're going to use this one plastic component across our complete product line,' if anything goes wrong with that plastic, now you have all these products that have to be recalled.

***FDA will confirm that manufacturers list recalls on their company Web sites.***

"So it's a problem of huge corporations consolidating a lot of stuff, and perhaps consolidating down to a few select suppliers," Szymanski continues. "If one supplier has a problem, it could go through the whole product line, resulting in a lot more products recalled."

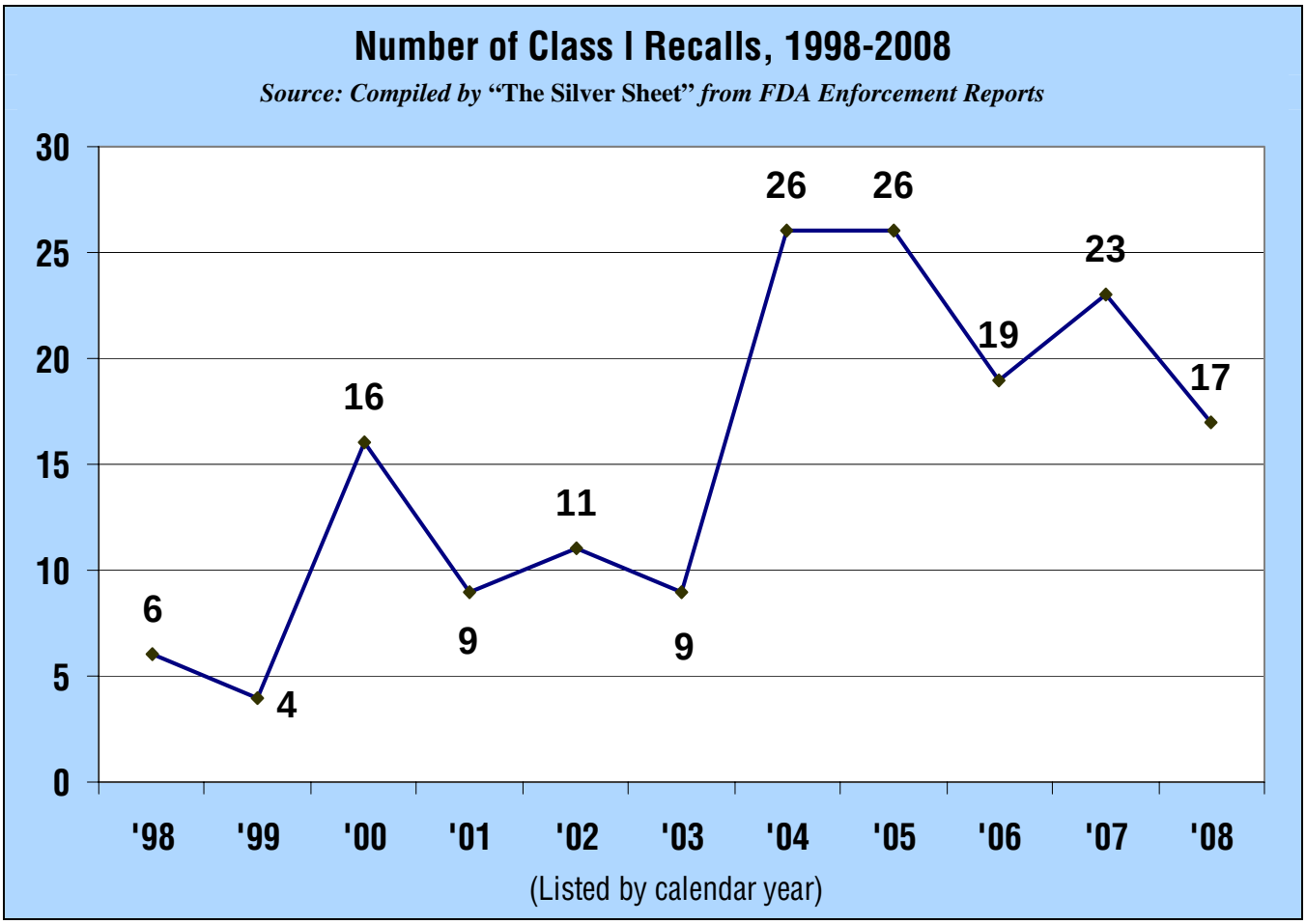
When large companies consolidate several small firms "under a main corporate umbrella, then you have the corporate umbrella looking at components or ingredients that they need to see if they can leverage a cheaper price by buying a larger amount," he says.

That, Szymanski notes, leads to poorer quality. If the manufacturer "wants a cheaper price, how does the supplier deliver that component with the same guarantee of good quality?" he asks.

### Siemens, Stryker, GE, Abbott, Medtronic, Biomet Posted Most Recalls In 2008

It should come as no surprise that the companies that conducted the most recalls last year were larger firms: Siemens, Stryker, General Electric, Abbott, Medtronic and Biomet (*See complete list of 2008 recalls, p. 12*).

All of those companies, except for Abbott, had more recalls in calendar year 2008 than in either of the previous two years.



Siemens led the pack with 46 recalls in 2008, compared with 10 in 2007 and 13 in 2006; Stryker saw 45 in '08, 15 in '07 and 6 in '06; General Electric had 35 in '08, 23 in '07 and 19 in '06; Abbott posted 24 in '08, 31 in '07 and seven in '06; Medtronic saw 24 in '08, 21 in '07 and 19 in '06; and Biomet had 24 in '08, 10 in '07 and one in '06.

### Stop Shipping Devices If Recall Is Necessary

Companies that are having problems with a device should immediately stop shipment of that product.

"You also need to do a recall investigation and stop shipment of any other product that could possibly be affected by your investigation," Szymanski says. "If you think [there's a problem with] a small component in a device and it's in a heart pacer, and you make other devices with that same component, then you need to stop shipping that so you can look at that to see if it's moved across products lines.

"Don't wait 30 days to finally determine that you have a recall of a different product," he adds. "That should be part of your investigation."

## 2008 Class I Recalls

- Am2pat's Sierra and B. Braun heparin lock flush solution. **Why?** Syringes may be contaminated with *Seratia marcescens*.
- Animas' battery caps used with insulin pumps and glucose monitoring systems. **Why?** Pump products exhibited an intermittent loss of power due to intermittent loss of contact between battery cap and battery canister, resulting in the device resetting.
- Boston Scientific's ***NexStent*** Monorail stent. **Why?** Detachment of the tip from the ***NexStent*** delivery system.
- Cardinal Health's ***Alaris*** pump module. **Why?** Inaccurate flow rate related to misassembled (missing, bent or broken) springs during the manufacturing or servicing of the mechanism assembly.
- Contract Medical Manufacturing's custom cranial implant kit. **Why?** Lack of assurance of sterility.
- Cordis' ***Dura Star*** and ***Fire Star*** dilatation catheters. **Why?** Slow deflation or no deflation.
- Covidien's ***ReliOn*** insulin syringes. **Why?** Packages labeled as an insulin syringe for use with U-100 insulin contain an insulin syringe for use with U-40 insulin.
- Integra LifeSciences's gravity-compensating accessory. **Why?** There is the potential for leakage under certain conditions.
- Levitronix's ***CentriMag*** primary system and backup console. **Why?** Interruption of ***CentriMag*** support may occur when using a ValleyLab ***Force FX-C*** electrocautery unit.
- Medtronic's ***SynchroMed EL*** infusion pump. **Why?** The pump motor stalls due to gear shaft wear.
- Medtronic's ***SynchroMed EL***, ***SynchroMed II*** and ***IsoMed*** infusion pumps. **Why?** Pumps used with the use of opioids, ***Baclofen***, pharmacy-compounded Baclofen and other drugs, as well as with other pharmacological admixtures, will cause the patient to develop an inflammatory mass.
- Medtronic's ***Indura IP*** intrathecal catheter; sutureless pump connector revision kit; and intrathecal catheter pump segment revision kit. **Why?** Potential for disconnection of the catheters from the catheter port on the pump, or occlusion between the sutureless pump connector and the catheter port on the pump.
- Pacific Consolidated Industries' mobile oxygen storage tank. **Why?** The firm received complaints of ruptured bourdon tubes that resulted in bellowed-out face gauges.
- Pharmacia Diagnostics' ***Healon D*** ophthalmic viscosurgical device. **Why?** Endotoxin levels above specifications have been noted in some syringes.
- Physio-Control's ***LifePak CR Plus*** automated external defibrillator. **Why?** The device was configured with incorrect software.
- Sun Med's ***GreenLine/D*** laryngoscope blades. **Why?** A breakage problem of the acrylic bundles at both distal and proximal ends of the light tube was detected.
- Vibe Technologies' ***Vibe*** Machine. **Why?** The device was marketed without FDA approval for claims that it cures cancer, infections and depression.

***Source: FDA Enforcement Reports***

Szymanski also urges firms to quickly contact their local FDA recall coordinator if a problem arises with a device.

"You should have that person's telephone number," he says. "If that recall coordinator is not in, you should know who his or her backup is. If you don't know who the backup is – or you call and you get a message that they're out – then call the FDA office general line and ask for the district director. They will get you someone to interact with fast."

Companies also need to develop a plan to ensure that the recalled product is returned quickly to the firm, if that is what will be required.

"A few years ago there were people being implanted with devices that had been recalled 120 days before," Szymanski says. "If you can get a device overnight to a hospital for implant, why did it take 120 days for that firm to get those devices back under their control?"

Once the devices are returned, firms will have to decide what to do with them.

"Are you going to destroy them? Are you going to recondition them? All those things need to be decided at the time you're doing a recall," Szymanski says.

## FDA 'Top 10' Chart of the Most Frequently Recalled Devices, 2002-2008

***For years, CDRH has kept track of the ten most frequently recalled device types. In the chart below, provided by FDA staff, the device listed in the top row had the most recalls in the given year, with the next most frequently recalled devices shown in the following rows.***

| FY '02 | FY '03 | FY '04 | FY '05 | FY '06 | FY '07 | FY '08 |
|---|---|---|---|---|---|---|
| Chemistry Analyzer | Data Processing Module | Electrosurgical Cutting & Coagulation Device & Accessories | Infusion Pump | Image Processing Systems – Radiological | Cardiopulmonary Bypass Heart-Lung Machine Console | Medical Charged-Particle Radiation Therapy System |
| Data Processing Module | Chemistry Analyzer | Nuclear MRI System | I.V. Administration Set | Blood Gas Measurement | Medical Charged-Particle Radiation Therapy System | Image Processing Systems – Radiological |
| Hip Prosthesis | I.V. Administration Set | Automatic External Defibrillator | Nuclear MRI System | Nuclear MRI System | Infusion Pump | Fluoroscopic X-Ray System & Solid State X-Ray Imager |
| Computed Emission Tomography | Infusion Pump | X-Ray Angiographic System | Heart Valve Allograft | Electrosurgical – Cutting/ Coagulation | Fluoroscopic X-Ray System | Orthopedic Manual Surgical Instrument & Impactor |
| Endosseous Implant | Differential Cell Counter | Chemistry Analyzer | Implantable Defibrillator | Cardiopulmonary – Heart/Lung | Glucose Test System | Automatic External Defibrillator |
| Glucose Oxidase | Fluoroscopic X-ray System | AC Powered Adjustable Hospital Bed | Automatic External Defibrillator | Dialyzer | Magnetic Resonance Diagnostic Device | Automated Differential Cell Counter |
| Cardiopulmonary Bypass Catheter | Computed Emission Tomography | Biliary Stent | Automated Differential Cell Counter | Infusion Pump | Endosseous Implant | Knee Prosthesis |
| I.V. Catheter | Coronary Stent | Infusion Pump | Continuous Ventilator | Catheters (Biliary, Wire, Introducers, Percutaneous) | Automated Differential Cell Counter | Ultrasonic Imaging System |
| Knee Prosthesis | Automatic External Defibrillator | Short-Term I.V. Catheter | Introducer Catheter | Fluoroscope X-Ray System | Continuous Ventilator | Computed Emission Tomography |
| Nuclear MRI System | Diagnostic Biliary Catheter | Differential Cell Counter | Intravascular Catheter | Defibrillators | Knee Prosthesis | Continuous Ventilator & Accessories |

In addition, FDA's Verdi says the agency will confirm that manufacturers list their recalls on their company Web sites.

"I've had consumers call me and say, 'I can't find anything about this recall on the company's Web site,'" he says. "So the recall should be posted on your Web site if you have one, and the consumer shouldn't have to hunt for a particular recall on your Web site."

### FDA: Planning Can Make Recall Go Smoothly

Many of the actions a firm would take during a recall can be mapped out before a recall even happens.

Szymanski recommends that manufacturers have a recall process already devised and conduct a mock recall to ensure that all employees understand the roles they will play.

"You should conduct experiments with that recall process," he says. "That means you bring in your senior people for an afternoon and give them a scenario – 'This went wrong with our device.'

"Then work it through the system, just as if a complaint came into the firm and you needed to make a determination whether you needed to get the product off the market," Szymanski adds. "Then simply track it through."

It's also important for the company to decide how it will quickly communicate a recall event.

"How will you contact the media? Are you going to do it by e-mail? Are you going to do it by telephone? Are you going to do it by press release? Are you going to do it by letter with your return card? You can do a combination of those," Szymanski says.

"All of those should be already in your process. If you need to issue press releases, you will want a template for the press release that is cleared through your attorneys," he notes.

### Clear Recall Letters Vital – Especially For Hospitals

Manufacturers also must issue recall notifications to physicians, hospitals, consumers and other users of the recalled device.

A recall notification letter must inform device users and purchasers to immediately stop using or distributing the nonconforming product. It should not contain irrelevant information or promotional material, FDA says ("The Silver Sheet" September 2007).

In addition, the words "Urgent Recall Notice" should appear on the heading of the notification letter, and the letter should explain the reason for the recall and the hazard the device poses.

***"You have an obligation to notify the individuals to whom you sold the product," FDA's Verdi says.***

"You have an obligation to notify the individuals to whom you sold the product," FDA's Verdi says. "Those, from the agency's perspective, are the number one people you want to notify.

"Also notify the hospital administrator or the hospital general manager, because in the eyes of the liability law, that's the person who is responsible for handling recalls," he adds. "The hospital may have nine people involved in recalls, but you need to notify that hospital administrator, because if none of those nine people do their jobs, this is the guy" who is going to be held responsible.

Firms also need to notify a hospital's purchasing department, risk managers and biomedical department.

Further, "if it's an implantable product, you need to make sure you notify implanting physicians, because they may have stock somewhere that the hospital isn't aware of," Verdi says. "They may have taken that stock back to their office in anticipation of implanting it."

### Limited Hospital Resources Make It Difficult To Sort Through Hundreds Of Recall Notifications

Bea Haupt, recall & safety manager for Inova Health System, says it's extremely important for a company's recall letter to be clear and succinct. Inova operates several hospitals in Northern Virginia.

"We get some recall letters and we truly don't know what to do with them," she says. "They don't tell me if we have to take the product off the shelf. Then we have to call the manufacturer. We don't have

time for that. The letter has to tell us the short-term implications, the long-term implications and whether [the product] should be taken off the shelf. We're struggling with this."

Because hospitals receive an average of 90 recalls per week, it's necessary that a firm's letter tells the facility exactly what it needs to do, says Ann Magee, a principal at the nonprofit Noblis Health Innovation.

"Each hospital department has a volume of information coming in," she says. "It could be everything from a light bulb, to the carpet, to the bed that the patient is in, to the medication that they're taking, and the hospital has to screen through all of that information.

***A hospital's firewalls may prevent a recall e-mail notification from reaching its destination.***

"Your recall is important, but it's one of many," Magee continues. "So when your recall letter information is not clear and straightforward, then they have to go to other facility staff to try to figure out what to do."

Magee says companies in their recall letters should instruct hospital employees to "quarantine and deface the boxes, because there have been instances where the recalled product has gotten on a loading dock and gone right back into the facilities that were the original purchasers."

Haupt says some manufacturers – including Johnson & Johnson subsidiary Cordis – send representatives to Inova hospitals to ensure that any recalled products have been pulled from their stock.

"We not only need a good recall letter telling us what we're supposed to do, but it helps when your reps come in here and help us pull it off the shelves," she says.

"Cordis will come in and get it off the shelf, and let us know who was impacted. There's a tremendous line of communication," Haupt says. "We have to have that in health care because our resources are very slim. We're just short-staffed all the time."

Cordis' principal QA engineer and recall coordinator, Hal Baden, says the company rigorously follows up on recalled products because they have a tendency to be shipped from one hospital to another.

"We always send an acknowledgement form that includes the exact lot numbers that we shipped to that particular facility," he says.

"The downside of that is, we know that there is some switching around within hospitals," Baden says. "Murphy's Law dictates that there are going to be recalled products at facilities that we never shipped to. So we have to send reps to do a clean sweep through all the hospitals, anyway, so we're sure that we get all the products off the shelves."

Haupt notes that she informs FDA if a company was not particularly helpful during a recall situation.

"FDA will ask us, 'Did they let you know? What was the date? What did the letter say? Did they tell you the lot numbers? Did they tell you the impact?'" she says. "I love to report back, 'Yes, they did.' I hate to say, 'You know what? I found this out through the grapevine. The manufacturer never communicated with us.'"

Magee reminds firms that "if hospitals are giving you bad scores, that means FDA is going to make you come back and re-issue that recall, and that's what makes the process become more drawn out. So understanding all the information hospitals need is very important."

### E-Mail Notifications Are OK, But Should Be Paired With Paper Recall Letter, FDA Says

FDA's Verdi says he doesn't object to manufacturers using an e-mail recall notification as an early warning, but it must be followed up with a paper recall letter.

An e-mail notification is "a great process to get out there and notify people in a hurry, but I still contend that a hard copy letter needs to go out," he says. "We're in a world where people have e-mail inboxes that sort mail and aren't identifying what should be looked at, and what should go to the 'trash' file or the 'next week' file, or the file you have to look at when you get a break.

"Since the recall process is a voluntary process, I'm not going to tell you that you can't" send an e-mail, he notes. "But I recommend that if you're going to do it, that [the e-mail is] your initial hit to get those

people early, because I'm all for telling people as fast as you can, as much as you can."

Inova Health System's Haupt warns that a hospital's firewalls may prevent an e-mail from reaching its destination.

"We have firewalls in our hospitals because of all the confidential information we're dealing with, so a lot of the e-mails never do reach me," she says.

Further, Noblis' Magee points out that employee turnover at a facility could prevent an e-mail recall notification from reaching its destination.

"Even hospitals that are really diligent with recall management aren't always so great at going in and removing employees [from their e-mail system] when they're no longer working in there or are no longer in that role," she says.

"So if you're relying on e-mail and it bounces back, you really do need to make sure you go to the next step, because you have to make the assumption that that e-mail probably did not get there."

FDA's Szymanski says a paper recall notification letter is necessary, otherwise the company won't be able to conduct appropriate effectiveness checks.

"The reason you're doing it through the mail is because you want a notification card coming back," he says. "Even over the phone, you're talking to them, and you have a response, and you can record it."

However, "if your e-mail generates an e-mail back from that person that says, 'This is what I've done, and I filled out the same thing as a response card,' you might be all right. But it still concerns me."

### Make Sure Follow-Up Recall Notifications Are Marked Properly, Experts Advise

Firms also must use caution when sending a facility a second or third recall follow-up notice.

"We had a recall recently where the supplier understood that they had to send a recall letter out three times," says Kevin Walters, manager of inventory for device supplier Owens & Minor.

The supplier "sent the letter out three times to everyone, whether they got a response back or not," he says. "Part of the problem is that when they sent the second letter, they put a current date on it and did not mark it 'Second Notice,' so it looked like a brand-new recall.

"The ideal thing to do is to send the original letter with the original date, and mark it 'Second Notice' or 'Third Notice,'" Walters adds.

Noblis' Magee recommends that manufacturers clearly mark any new information that wasn't included in the original recall notification.

"When a firm starts attaching 40 to 60 pages worth of lot numbers and a facility employee has to go through it, literally, and compare it against the one that previously went out, it's just monumental," she says.

"So if you're going to send an update, it really is very helpful to state specifically what the new information is," Magee says. "Then follow that with what was previously issued in the previous recall notification so they don't have to search through the whole thing to find out that they already took the product off the shelf. You can imagine how quickly someone could get frustrated by that."

### States Will Soon Have Access To FDA Database

Health and agriculture departments in all 50 states will have rapid access to FDA's Recall Enterprise System (RES) by Sept. 30.

RES is a database that includes the full array of communications between the agency's district offices and headquarters concerning product recalls. It allows FDA staff to look up a recall event and see the continuing timeline of activity on it.

Since the agency began using the system internally in November 2002, thousands of recall events involving devices, drugs, biologics, foods and veterinary medicines have been entered into the database.

During a meeting in St. Louis last August, the agency promised the state officials that they would be able to use RES by the end of the current fiscal year, FDA's Szymanski says.

"Certain states said during the St. Louis meeting that if they have access to [information about firms]

that recall a product in their state, they would want to ... make sure it's no longer on the shelf," he says.

In addition to RES access, state officials asked for "electronic downloadable [recall] audit forms, because the states want to know the distribution [of recalled products] within their state, and they want to immediately go out and do their own audits," Szymanski says.

He pointed out that the extra help from the states could free up FDA to better use its resources elsewhere.

For example, if a problem device "came into the state of Montana, the state is going to go out and look [to see if it's still being sold], regardless of whether FDA's been there or not," Szymanski says.

"So if they're going to go out and look at it, maybe FDA can go to a different state that's not doing it and concentrate there."

*– Shawn M. Schmitt (sm.schmitt@elsevier.com)*

# 2008 MEDICAL DEVICE RECALLS

***The following list of medical device recalls was compiled by* "The Silver Sheet"** ***from FDA's weekly* Enforcement Report** ***issued during calendar year 2008. Entries are listed alphabetically by company. Class I recalls are shaded.***

***There can be a delay of weeks or months between a company's recall and its appearance in the* Enforcement Report.** ***Therefore, some of the recalls on the following list may have taken place prior to 2008, while some recalls that occurred during the year are not included because FDA has not yet published them in an* Enforcement Report.** ***The list below includes only those recalls pertaining to medical device products; recalls for non-medical device products that are under the jurisdiction of the Center for Devices and Radiological Health, such as laser pointers, tanning beds and airport X-ray systems, have been excluded.***

| Manufacturer | Product | Class | Reason |
|---|---|---|---|
| 3M | ***Unitek*** Stainless Steel Permanent Molar Crowns | III | Packaging incorrectly identified the product as "***Unitek*** stainless steel primary molar crowns." (Z-0569-2008) |
| Aadco Medical | ***Rayshield*** Frame Mounted Overhead X-ray Barrier | II | Screws may become loose from the mounted shield, compromising stability. (Z-0552-2008) |
| Abaxis | ***Piccolo*** Chemistry Analyzer | II | The product will recover $tCO_2$ at approximately 5-7 units high relative to 03-10. (Z-2286/2287-2008) |
| Abbott | ***FreeStyle*** Blood Glucose Monitoring System Test Strips | II | Flaws in strip voltage continuity may result in frequency of an "Error 3" ("Er3") message display and unreadable strips. This issue has the potential for creating a delay in generating blood glucose results and to delay diabetes management, potentially leading to either hypo- or hyperglycemia, and their associated complications. (Z-1813-2008) |
| Abbott | ***AxSYM*** Ultrasensitive hTSH II Master Calibrators Microparticle Enzyme Immunoassay | II | High-control-value out-of-range after calibration. An increased frequency of high control values beyond the upper limit of the range specified by the package insert. (Z-1566-2008) |
| Abbott | Various ***TDx/TDxFLx*** and ***AxSYM*** Reagents | II | There is a decrease in the calibrator A-to-F span. (Z-0928/0930-2008) |
| Abbott | ***AxSYM*** Digoxin II Reagent Pack | III | The instrument might require installation of the ***AxSYM*** Digoxin II assay file. (Z-0297-2009) |
| Abbott | ***Flexiflo*** Quantum Pump Set with Piercing Pin and Flush Bag | II | Product was incorrectly labeled as "Top-Fill Enteral Nutrition Bag" instead of "***Flexiflo*** Quantum Pump Set." (Z-2305-2008) |

| Manufacturer | Product | Class | Reason |
|---|---|---|---|
| Abbott | ***Cell-Dyn Sapphire*** Hemoglobin Reagent Analyzer Syringes | II | Insufficient lubrication of the plunger tip may cause syringes to fail at installation or shortly thereafter. (Z-0301-2008) |
| Abbott | ***AxSYM Ausab*** Reagent Pack | II | Reagents were manufactured with an incorrect ratio of two key components, which could result in both false-reactive and false-nonreactive specimens. (Z-0127-2008) |
| Abbott | ***Cell-Dyn 1800*** System | II | Hemoglobin results vary more than expected across the range of claimed operating temperatures. (Z-0455-2008) |
| Abbott | ***Cell-Dyn*** Hemoglobin Reagent Syringe | II | Hemoglobin background count may be out-of-specification after installation of new reagent syringes with packaging dates between May 8, 2007, and Nov. 29, 2007. (Z-1165-2008) |
| Abbott | White Blood Cell Reagent | II | The reagent was confirmed positive for *Pseudomonas* contamination. (Z-1103-2008) |
| Abbott | ***AxSYM*** Rubella IgG Reagent Pack | III | There were assay calibration failures due to error codes related to elevated "Calibrator A" (or "Master Calibrator 1") rates being too high. (Z-2175-2008) |
| Abbott | Clinical Chemistry Creatine Kinase | II | There was a decrease in quality control and/or patient results; an increased imprecision; or "Error Code 1054" (unable to calculate results, reaction failure). (Z-1109-2008) |
| Abbott | Clinical Chemistry ICT Calibrator | III | Use will generate an acceptable but low calibration slope. When quality control (QC) is run to verify the calibration, potassium QC results may be below acceptable QC ranges. (Z-1166-2008) |
| Abbott | Clinical Chemistry Phenytoin | II | Reagent does not maintain an onboard stability of 28 days as stated in the phenytoin package insert. In addition, the 14-day calibration interval is also not being met. (Z-2059-2008) |
| Abbott | ***Architect iSystem*** Assay CD-ROM | II | The lower-limit flag for auto-dilution protocol 3 (amniotic fluid) was set too low (15 ng/mL). The assay labeling indicates that the limit flag should be set no lower than 20 ng/mL (Z-0299-2008) |
| Abbott | ***AxSYM*** Drugs of Abuse/Toxicology Assay | III | If the positive and negative interpretation cutoff parameters (116/117) are edited after installation of the revised assay file, "VRTX Error #0002" in Task 40 is generated, and the instrument locks up when it attempts to report an ***AxSYM*** amphetamine/methamphetamine II patient result. (Z-1462-2008) |
| Abbott | ***Cell-Dyn Sapphire*** Hematology Analyzer | II | Exposed wire resulted in minor electrical shock and burn to the service technician. (Z-0306-2009) |
| Abbott | ***Architect c8000*** Processing Module | II | Software defect can allow tests ordered for one sample to be aspirated from a different sample, reporting erroneous results for the affected sample. (Z-2231-2008) |
| Abbott | ***Cell-Dyn Sapphire*** Hematology Analyzer | II | Table in LIS specification depicting the association between record ID and numerical result label is incorrect. If a record ID is used to configure the system for mapping, results will come out nonsensical. (Z-2139-2008) |
| Abbott | ***Architect i1000SR*** System Assay CD-ROM | II | When running the automated dilution protocol with the assay files "CMV IgG" or "Toxo IgG" on the system, a software error is generated and the instrument stops running. (Z-2239-2008) |

| Manufacturer | Product | Class | Reason |
|---|---|---|---|
| Abbott | ***Sequoia*** Spinal System Surgical Kits | II | The polyaxial screw head may dissociate from screw shaft during surgery. Also, the polyaxial screwdriver is experiencing difficulty, such as broken/bent driver shafts, difficulty attaching screws to the driver and jamming of the collet. (Z-1479-2008) |
| Abbott | ***InCompass*** and ***PathFinder*** Spinal Fixation System T-Handle Drivers | II | Disassembly driver components during surgery, dropping the closure top into the surgical site. (Z-1592/1593-2008) |
| Abbott | ***PathFinder*** Cannulated T-Handle Bone Awl | II | Tips on the awl may bend or break prematurely. (Z-1784-2008) |
| Abbott | ***Viking*** Guiding Catheter | III | The part number on the product label packaging may not match the product. (Z-1633/1634-2008) |
| Abiomed | ***Abiocor*** Implantable Heart Replacement Kit System | II | Subassembly incorrectly aligned. (Z-2304-2008) |
| Abon Biopharm | Fisher Healthcare ***Sure-Vue*** Serum/Urine hCG-STAT | II | The test, when interpreted at extended read times, may exhibit sensitivity to patient samples containing hCG at levels well below the cut-off, potentially resulting in a false-positive interpretation by the user. (Z-1118-2008) |
| Acacia Engineered Products | Isotechnology | II | The firm distributed an unapproved medical device. (Z-2348-2008) |
| Accellent | Bausch & Lomb ***Millennium*** Phacoemulsification Needles | II | The directions for use are printed with the incorrect symbols to indicate the product is packaged as sterile and non-reusable. (Z-2044/2052-2008) |
| Accellent | Orthopedics Echo Hip Instrumentation Exact Slotted Stem Inserter | II | The instrument will not mate with its stem. (Z-1318-2008) |
| Accuray | ***CyberKnife*** Robotic Radiosurgery System | II | Couch may move unexpectedly, which may result in patient impacting the linear accelerator. (Z-1862-2008) |
| Accuray | ***CyberKnife*** Robotic Radiosurgery System | II | Sample beam data – which should not be used to treat patients – may differ from actual radiation output of an installed product, which may be used by users. (Z-2056-2008) |
| Acumed | Cortical Screw | II | Package of 3.5 mm X 32.5 mm cortical screw may contain 3.5 mm X 5 mm cortical screw. (Z-2155-2008) |
| Acumed | Various Locking Plate Products | II | Product sterility may be compromised. (Z-2108/2132-2008) |
| Acumed | Modular Shoulder Body Assembly | II | The packages for modular shoulder body assembly left (SH-1540L-S) and modular shoulder body assembly right (SH-1540R-S) may contain assemblies for the opposite side, as indicated. (Z-0447-2009) |
| Acumed | ***Osteo-Clage*** Cable System Package Assembly | II | Cables of incorrect diameter were used in product assembly, resulting in the sleeve not being able to bind to the cable after crimping. (Z-2140-2008) |

| Manufacturer | Product | Class | Reason |
|---|---|---|---|
| Acutronic Medical Systems | Datex-Ohmeda Neonatal Enhancement for the ***Engström*** Carestation | II | Neonatal flow sensors supplied for use with the carestation may result in the sensors providing invalid values and alarm messages when exposed to high-flow rates. (Z-1526-2008) |
| Advanced Bionics | ***Precision*** Implantable Pulse Generator Kit | II | Corruption of internal memory component results in an inability for the physician to reprogram the IPG with firmware version prior to Revision 3.02. When this occurs, the IPG will report an error code of "10h0" or "00h0" through the remote control. (Z-0960/0961/-2008) |
| Advanced Bionics | ***Precision*** Charger | II | Patients have reported receiving second- and third-degree burns in the area of charging while using charger. (Z-0271-2009) |
| Advanced Sterilization Products | ***Sterrad*** Sterilizers | II | Recalling firm has decided to discontinue dissemination of compatible medical device reference lists and instrument assessment activities. (Z-0844-2008) |
| Advanced Sterilization Products | ***Sterrad 100S***, ***50***, ***200*** and ***NX*** Sterilizers | II | Updated user guidance has been issued. (Z-0845/0848-2008) |
| Advanced Sterilization Products | ***Sterrad 100S***, ***50*** and ***200*** Sterilization Systems; ***Sterrad NX*** and ***100NX*** Sterilizers | II | Oil mist filter fails, allowing oil mist to be emitted into the vicinity of the sterilizer, which may result in the release of a mist, haze or smoke. (Z-1628/1632-2008) |
| Advanced Sterilization Products | ***Sterrad 100S*** Sterilizer | II | Sterilizer doesn't detect when an injection takes place without hydrogen peroxide being transferred to the vaporizer bowl. Also, the sterilizer doesn't detect an obstruction in the door travel path while the door is closing. (Z-0340-2009) |
| Advanced Sterilization Products | ***Sterrad NX*** Sterilizer | II | There is a component defect in some of the UV lamp power supplies used in certain sterilizers. This defect can potentially cause the hydrogen peroxide monitor to give inaccurate readings. (Z-0484-2009) |
| Aesculap | ***Caspar*** Titanium Aneurysm Clip Appliers | II | The inner rod of the applier may corrode and break. (Z-0708/0709-2008) |
| AGA Medical | ***Amplatzer*** Delivery System and Sizing Balloon II | II | Outer pouch seal integrity may be compromised. (Z-2192/2193-2008) |
| AGFA | ***Impax*** 6.2.1 Network Gateway Server | II | The device could not transmit imaging data, because a key value needed for data transmission was incorrectly entered in the affected units. (Z-1306-2008) |
| AGFA | Various ***Impax*** Picture Archiving Systems | II | The orthopedic planning X-ray images for one patient are misidentified as the images for another patient. (Z-1307-2008) |
| AGFA | ***Impax*** 6.x Clients | III | The client failed to "refresh" the image area upon receiving a study retrieved from archive. The system also erroneously displays this study retrieved from archive as the "active" study. (Z-2180-2008) |
| AGFA | ***Impax*** 4.1, 4.5, 5.0, 5.1 5.2, 6.0 and 6.2; ***Web1000*** Versions 3.1, 4.1 and 5.1 | II | Due to a Software mismatch, data can be lost. (Z-1243/1244-2008) |
| AGFA | ***Impax*** 6.2.1 System | II | Text and images may not be synchronized. (Z-1245-2008) |

| Manufacturer | Product | Class | Reason |
|---|---|---|---|
| AGFA | ***Impax*** Cardiovascular Suite Results Management Nuclear Reporting Module, Outbound Report | II | The outbound report software produces an outbound report (text version) that does not contain all the clinical content elements present in the PDF version of the report, also generated on the nuclear cardiology-reporting module. (Z-1349-2008) |
| AGFA | ***Drystar Axys*** Hardcopy Printer | III | The "Film Calibration" setting on the printers was set to the default "Off" position instead of "On." (Z-2136-2008) |
| Alcon | ***ILM*** Forceps | III | Forceps are prone to corrosion and possibly premature fracture and/or malfunction. (Z-1461-2008) |
| Alcon | ***PurePoint*** System | II | Indications for use unapproved by the Food and Drug Administration are included in the PurePoint Laser System Operator's Manual, Catalog Number 8065751131, Revision B. (Z-0274-2009) |
| Alcon | ***Monarch II*** IOL Delivery System | II | Delivery cartridge for implanting intraocular lenses is mislabeled and may result in complicated insertion and damage to the lens. (Z-2441-2008) |
| Alfa Wassermann | ***Ace*** and ***Ace Alera*** Reagents, Controls and Calibrators. | II | Internal studies observed occasional unexpected outlier results in whole blood samples tested for Hemoglobin A1c using the EZA1c reagent on the clinical chemistry systems. (Z-0482-2009) |
| Allen Medical Systems | ***C-Flex*** Polar Head Positioner | II | Handle jamming in the open position, preventing the device from adequately supporting the head during spinal surgery. (Z-1478-2008) |
| Allez Spine | ***Laguna*** and ***Del Mar*** Pedicle Screw Systems | II | The cleaning, decontamination and sterilization procedures specified in the "Instructions for Use" are incorrect. (Z-1819/1820-2008) |
| Allez Spine | Pedicle Screws of the ***Laguna*** Pedicle Screw System | II | The screw shank portion separates from the pedicle head portion of the Size 8 pedicle screw when torquing down the single-piece locking nut during implantation. (Z-0186/0191-2008) |
| Allez Spine | ***Laguna*** Pedicle Screw System | II | A partial displacement of screw shank when used in combination with the single piece locking nuts. This partial displacement of the screw shank could lead to total separation and failure of the construct. (Z-2060/2078-2008) |
| Allez Spine | ***Laguna*** and ***Del Mar*** Pedicle Screw Systems Cross Connectors | II | The action was taken voluntarily as a result of a warning letter issued to Allez Spine by the FDA. The company decided it could better address FDA's concerns regarding current good manufacturing practice requirements of the quality system without any product in the market, so it could focus all of its efforts on responding to the FDA. (Z-0153/0155-2009) |
| Allmed Medical Products | ***Medline RF*** Detect Sterile X-ray Detectable USP Type VII Gauze | II | There is the potential for the RFID tag to separate from the retaining pouch. (Z-2321-2008) |
| Alpha Omega Services | ***Flexiguide*** Needle | II | There is the potential for the needles tip to leak, thereby breaking the sterile boundary and possibly contaminating other devices with body fluids. (Z-0166/0170-2009) |
| Am2pat | Sierra and B. Braun Heparin Lock Flush Solution | I | Syringes may be contaminated with *Seratia marcescens*. (Z-0827/0841-2008) |

| Manufacturer | Product | Class | Reason |
|---|---|---|---|
| Ambu | Positive End Expiratory Pressure Valves | II | Medical device for respiratory care may leak and not register accurate flow settings that affect patient respiration. (Z-0533/0536-2008) |
| Amerasia Industries | Anesthesia Breathing Bags | II | During setup and potentially during procedures, the breathing bag can become separated from the taped bushing that is part of the breathing bag assembly. (Z-2324-2008) |
| American Medical Systems | ***GreenLight HPS*** System, Surgical Laser System and Accessories | II | Some products were issued without thermal protection switches. (Z-0130-2008) |
| American Medical Systems | ***In-Fast*** Ultra Kit with Polypropylene Suture | II | The ***In-Fast*** Ultra Transvaginal Bladder Neck Support System may contain only one bone screw, but should contain two as indicated on the labeling. (Z-1235-2008) |
| American Medical Systems | ***AMS 700 CX MS*** Pump IZ | II | The package indicated that the device is an 18 cm pre-connected MS pump while it is actually an 18 cm ***Ultrex*** pre-connected MS pump. (Z-2461-2008) |
| AmniSure International | ***ROM Test*** | II | Weak true-positive or false-negatives in ruptured fetal membranes may occur due to a "hook effect." (Z-0120-2008) |
| AMO Manufacturing | ***WaveScan WaveFront System*** | II | Inaccurate measurements may be generated by the device, which could result in improper treatment and deterioration of patient eyesight. (Z-2310-2008) |
| AMS Innovative Center | ***GreenLight HPS*** Fiber Optic | II | The knob used to finely control the direction of the laser energy may break. (Z-0131-2008) |
| AngioScore | ***AngioSculpt*** PTCA Scoring Balloon Catheter | III | Labeling on product pouch indicates the wrong size; the correct size is on the product carton. (Z-0591-2008) |
| Animas | ***OneTouch*** Ping Glucose Monitoring System | II | Displays old, inaccurate values for bolus amount delivered and amount of planned bolus totals. (Z-0283-2009) |
| Animas | Battery Caps Used with Insulin Pumps and Glucose Monitoring Systems | I | Pump products exhibit an intermittent loss of power due to intermittent loss of contact between battery cap and battery canister, resulting in the device resetting. (Z-2090/0294-2009) |
| Apex Biotechnology | ***Assure 3*** Blood Glucose Test Strips | II | The Level 1 control solution range printed on the 50-count test strip bottles is incorrect. The range printed on the bottle is 62-54 when it should be 62-94. (Z-0699-2008) |
| Apogee Medical | Intermittent Catheter | II | The catheter tip may have been inadvertently cut, which could cause trauma to the urethra upon use. Also, the sterility of the product could be compromised. (Z-2390/2394-2008) |
| Applied Cytometry | ***Cytomics FC 500*** Flow Cytometry System | III | If the cytosettings are not refreshed or restarted during data importation, the output will include old and new data. (Z-0958/0959-2008) |
| Applied Cytometry | ***Cytomics FC 500*** Flow Cytometry System | II | In certain modes the protocol will not initially display the correct data in some plots. In addition, when running EWL files, any edited Sample ID1 is not automatically updated in all tubes in the panel. (Z-2016/2033-2008) |

| Manufacturer | Product | Class | Reason |
|---|---|---|---|
| Applied Medical Resources | ***Silhouette Xtraflo*** Device with SL-6 Hydrophilic Coating | II | Possible movement or dislodgement of the positioner marker band during use. (Z-2219/2224-2008) |
| Applied Medical Resources | Separator Abdominal Access System; Lap Banding Kit; Lap Roux-EN-Y Kit | II | Potential inability to insufflate through the stopcock. Under certain circumstances, a flexible elastomeric component inside the 15 mm trocar can stretch into a configuration that blocks the flow of insufflation gas ($CO_2$). (Z-0023/0029-2009) |
| Arco Electronics | ***CES Ultra*** Cranial Electrotherapy Stimulator | II | No FDA clearance for the .35Hz/.45Hz frequency option on the device. (Z-0712-2008) |
| Argon Medical Devices | ***ArgoGuide*** Hydrophilic NiTi Guide Wire | II | Hydrophilic guide wires may exhibit degradation of blue Pebax cladding causing particulate to dislodge. (Z-0882/0891-2008) |
| Arizona Device Manufacturing | ***Bravo*** pH Capsule with Delivery System | II | The capsule may not detach from the delivery system following attachment to the esophageal wall. (Z-0517-2008) |
| Arjo | ***Maxi Move*** Patient Lift | II | There is the potential for unintended dislocation of the lock-and-load hanger assembly from the T-bar attached to the lifter jib of the patient lift. (Z-2470-2008) |
| Arjo | Medical Infrared Hand Control System | II | The ceiling lift may not stop lateral movement after releasing the left (or right) action button on a ceiling lift equipped with an infrared hand control. (Z-1233-2008) |
| Arjo | ***Ambulift*** | II | The armrests of the lift chair may push up, allowing the patient to slip down and out of the seat. (Z-1650/1651-2008) |
| Arrow International | ***ACAT*** Intra-Aortic Balloon Pumps | II | Leak may occur in the helium drive system. (Z-0549/0550-2008) |
| Arrow International | Temporary Pacing Catheter Introducer Sheath Kits | II | The kits do not contain a complete 6 Fr introducer assembly. (Z-1907/1908-2008) |
| Arrow International | ***Cannon*** Catheter II; ***Cannon II*** Plus; ***Edge*** Hemodialysis Catherization Set | II | The tips may not have been adequately welded to the catheter body. (Z-2242/2285-2008) |
| ArthroCare | ***Topaz XL ArthroWand*** with Integrated Cable Wand | II | Device sterility may be compromised due to punctures in the plastic tray during shipping. (Z-1657-2008) |
| ArthroCare | ***ArthroWand*** Covator with Integrated Cable Wand | II | Product is not secure in packaging, and movement may damage the product or render it non-sterile. (Z-2309-2008) |
| Asia Expo Consultants | Acupressure/Acustimulation Wrist Bands | II | Product was marketed before FDA cleared its 510(k) application. (Z-1821-2008) |
| Atmos Medizintechnik | Power Supply | II | External battery chargers used with the Version 29 ***Vista*** negative pressure wound therapy pumps are failing to properly charge the pump's battery. (Z-0162-2009) |
| Atrium Medical | Various ***HydraGlide*** Catheters | II | Heparin-coated catheters were manufactured with heparin allegedly contaminated with oversulfated chondroitin sulfate. (Z-1830/1853-2008) |

| Manufacturer | Product | Class | Reason |
|---|---|---|---|
| Avail State College | ***InfoV.A.C.*** Canisters | II | The port on the canister that connects to the suction pump tubing was partially or fully occluded with plastic. (Z-2439/2440-2008) |
| Availmed | ***Mach 1*** Guide Catheter | III | Catheters were mislabeled with the incorrect device length. (Z-1300/1305-2008) |
| B. Braun | Smallbore T-Port Extension Set | II | Product was assembled incorrectly and connected to the wrong part. (Z-0199-2009) |
| B. Braun | Various Pump Sets, Metrisets and Burette Sets | II | Incorrect burette was packaged with the product. (Z-2407/2414-2008) |
| B. Braun | ***Diapact CRRT*** Assembled Kit HF/HD with Manifold and Standard Spike | III | Faulty tubing does not prime machine as intended. (Z-1035/1036-2008) |
| B. Braun | ***IsoMed*** Refill Kit | II | Kit was released using incorrect endotoxin specification limits. (Z-1903-2008) |
| BHM Medical | ***Nautica*** Mattress Stretcher | II | Repeated use of the ratchets that lock the position of the back and leg rest of the stretcher may damage the retention pin that prevents the latch from disengaging from the anchor system. This would allow the backrest to pivot freely down to the floor. (Z-1234-2008) |
| BHM Medical | Medical Scales | II | The locknut on the scales may loosen during use, and allow the hanger bar assembly of the patient lift to detach and fall. (Z-1135/1136-2008) |
| BHM Medical | ***Medi-Lifter III Plus*** and ***Summit*** Total Lifts | II | The mast scale load cell assembly may fracture and allow the mast/boom to fall. (Z-1557-2008) |
| BHM Medical | ***Kwiktrak*** Gate System | II | The gate locks may open even though the corresponding tracks are not properly aligned. (Z-2434-2008) |
| BHM Medical | ***Maxi 500*** Patient Lifts | II | The pivot bolt that attaches the hanger bar to the scale of the patient lift can break, resulting in the hanger bar falling. (Z-0322/0323-2009) |
| BHM Medical | ***Maxi 500*** Patient Lifts | II | If the spring pin is not properly reinstalled after maintenance, the pivot bolt could unscrew by itself within a limited period of time resulting in a hanger bar detachment. (Z-0412/0413-2009) |
| BHM Medical | ***Maxi Move*** | II | The battery pack has a defective connector that could lead to the inability of the battery pack to recharge and/or cause a short circuit, resulting in smoke emission. (Z-0503-2009) |
| BainLab | ***VectorVision Sky*** Navigation Platform | II | The diameter of the cables used for installation is too small for the applied current. If an internal short circuit is produced, the medical power supply will not shut down automatically and will continue to deliver current, which could result in overheating cables. (Z-2209-2008) |
| BarcoView | ***Barco*** Surgical Display | II | The front protective cover may loosen and completely fall off. (Z-0276-2009) |
| Bard | Recovery Cone Removal System | II | The product has a potential for the handle to detach. (Z-1854/1855-2008) |

| Manufacturer | Product | Class | Reason |
|---|---|---|---|
| Bard | Dual Port Wizard Low-Profile Replacement Gastrostomy Device | II | Gastrostomy device anti-reflux valve may allow leakage from the stomach. (Z-0416/0437-2009) |
| Bard | ***Vacora*** Biopsy Vacuum Assisted Biopsy Probe | III | Some of the probe thumb wheels may fracture when fired using the prime/pierce option. (Z-0183-2009) |
| Barrx Medical | ***HALO360+*** Ablation Catheter | II | Some units may contain the wrong filter, which does not have the proper lock and may result in a leak. (Z-0192-2009) |
| BatteryZone | ***LifeCell*** | II | Marketed without 510(k) approval. (Z-0523/0524-2008) |
| Baxa | ***Exacta-Mix 2400*** and ***600*** | II | Flush solution from TPN compounder may be added to patient's TPN bag. (Z-1370/1371-2008) |
| Baxter | Single-Day Infusor Portable Elastomeric Infusion System | II | Leaks at the tubing flow restrictor connection to either the coupler or the male luer during filling. (Z-0588-2008) |
| Baxter | ***RenalSoft*** Patient Management Software Suite | II | The heparin bolus value is displayed on pre- and post-treatment reports for patients with "No Heparin" orders, and withheld medications are incorrectly displayed as administered on the pre-treatment report. (Z-0527/0528-2008) |
| Baxter | ***Logix*** TPN Software Solution | II | Software anomaly results in inaccurate information being printed out on the delivery report, even though the compounder performed the compounding correctly. (Z-1640-2008) |
| Baxter | ***FloSeal*** Endoscopic Applicator | II | There is a potential discoloration of the ***FloSeal*** material. (Z-2340-2008) |
| Baxter | Auto Syringe ***AS50*** Infusion Pump | II | Nonconforming electrostatic discharge grounding squares may cause the pump to be susceptible to shorting-out of circuitry, resulting in a loss of audio, and/or interruption of therapy. (Z-0152-2009) |
| Baxter | ***HomeChoice*** and ***HomeChoice PRO*** Automated Peritoneal Dialysis Systems | II | If the system is powered down or a power failure occurs during a fill cycle, the system may not record the last one to four pump strokes infused into the patient when the power is restored. This situation may create a potential unrecorded delivery of approximately 15 mL to 60 mL of fluid being infused into the patient. (Z-0946/0947-2008) |
| Baxter | ***Hep-Lock*** Heparin Lock Flush Solution | II | Increase in adverse events for single- and multi-dose heparin injection products, which use the same active pharmaceutical ingredient source as ***Hep-Lock*** products. (Z-1384/1393-2008) |
| Bayer | ***Contour TS*** blood glucose monitoring system and test strips | II | Inaccurate test strips results: Results in blood glucose readings with a positive bias are outside the product specifications. Patient test results may demonstrate results 5% to 17% higher. (Z-0931/0932-2008) |
| BD | ***MultiSET*** Flow Cytometry Software | II | Software error results in inaccurate display result statistics. If the user adjusts the lymph gate or attractors in the "Lab Report" view without using the "Manual Gate" function, the statistic results will not be updated to match the adjusted gate. (Z-0570-2008) |
| BD | ***FACS*** Sample Prep Assistant II | II | ***SPA II*** devices manufactured with the affected product motor-control board may exhibit suboptimal mixing performance. (Z-0526-2008) |

| Manufacturer | Product | Class | Reason |
|---|---|---|---|
| BD | ***FACSDiva*** Software | II | Values might not update in statistics views after certain functions are performed in a worksheet. (Z-1530-2008) |
| BD | ***FACSDiva*** Software | II | When a data file containing one or no fluoresence parameters is exported, the software will automatically apply compensation to this file and all subsequently exported files. (Z-1525-2008) |
| BD | ***Ventana*** Image Analysis System | II | The software upgrade from February 1, 2007, may not have been completed. (Z-0571-2008) |
| BD | Difco and Lee Laboratories *Shigella* Antiserum Poly Group B | II | In vitro diagnostic test reagent for identification of *Shigella* bacteria in patient samples may cause false-negative results. (Z-1527/1528-2008) |
| BD | ***Vacutainer*** Push Button Blood Collection Sets with Pre-Attached Holder | II | The safety mechanism cannot be activated; thus the needle cannot retract into the rear barrel. (Z-0589/0590-2008) |
| BD | Various Difco *Neisseria Meningitidis* Antisera Groups | III | Exhibits cross reactivity with *Neisseria meningitidis* group W135. (Z-1559/1562-2008) |
| BD | Syringe | II | Presence of open seals. (Z-2374-2008) |
| BD | ***Mentor*** Aseptic Transfer Set | II | Set contains a component, the BD 60 mL Luer-Lok Syringe, which is under recall due to a package integrity issue. (Z-0407-2009) |
| BD | ***Visitec*** High Viscosity Injector | II | Product labeled as "4 mm High Viscosity Injector Tip" contains a 6 mm tip. (Z-0022-2009) |
| BD | Syringe Luer Lok Tip | II | The convenience trays may have open seals, which can adversely impact tray sterility. (Z-0914/0195-2008) |
| BD | ***Visitec*** Disposable Instrument Capsulorhexis Forceps | II | Metal particulates present. (Z-2433-2008) |
| Beckman Coulter | ***LH750*** and ***LH780*** Analyzers; ***LH500*** Series System; ***GEN*S*** System | II | Patient misidentification can occur when a positive identifier ("Sample ID" or "Cassette/Position") is manually edited to a positive identifier that is already in the "To Do" list. The workstation will accept the entry and no error message will be generated, creating two samples with the identical positive identifier. Also, when manually entering a patient ID, if a blank space is entered between the characters in the "Patient ID" field, the system will only accept the characters before the space. (Z-0312/0315-2008) |
| Beckman Coulter | ***Flow-Count*** Fluorospheres | II | Sporadic absolute count recovery failures with assayed control cell products. Additionally, the device has experienced secondary fluorescent populations containing more than 20% of the total population, as stated in the "Evidence of Deterioration" section of the package insert. (Z-0525-2008) |
| Beckman Coulter | Various ***Synchron*** and ***UniCel*** Devices | II | Intermittent failure of stirrer motor. Stirrer motors can stall without any flags or motion errors. (Z-1094/1101-2008) |
| Beckman Coulter | ***Access*** Ultra Sensitive Insulin Assay Kit | II | False-negative results when used to test serum samples. (Z-1160-2008) |

| Manufacturer | Product | Class | Reason |
|---|---|---|---|
| Beckman Coulter | ***Cytomics FC 500*** Flow Cytometry System with Data Innovations Instrument Manager | II | Labeling provided by two integrated software systems is not clear enough to avoid potential demographic and sample-type mismatches under certain conditions. (Z-1529-2008) |
| Beckman Coulter | Various ***Access***, ***Synchron*** and ***UniCel*** Devices | II | Premature failure of the waste pump tubing. (Z-2384/2387-2008) |
| Beckman Coulter | ***Synchron*** Acetaminophen Reagent | II | Reagents manufactured with contaminated heparin have shown a negative bias in performance between the assay made with contaminated and uncontaminated heparin. (Z-2405-2008) |
| Beckman Coulter | ***Vidiera*** Nucleic Sample Preparation | II | When the transfer volume is not within the set range, the ***Vidiera*** software does not report sample exclusion and does not flag the excluded sample in the "Run Results" report. (Z-0454-2009) |
| Beckman Coulter | ***Access*** Power Supply Assembly Sled | II | Electrical-grounding failure. During manufacturing, internal testing found one instrument with an intermittent failure of the electrical grounding. The source of the problem was traced to inadequate soldering. (Z-1183-2008) |
| Benchmark Electronics | Blood Glucose Meter | II | Meters manufactured after January 31, 2007 could exhibit meter-display damage if dropped on a hard surface. These meters could exhibit unreadable lot number fields and date/time fields, in addition to complete blanking of the numerical reading portion of the display. (Z-0112-2008) |
| Benchmark Electronics | ***iCon*** Patient Programmer | III | Programmers were not properly loaded with application software. The application software is needed for a patient programmer to synchronize and bond with a neurostimulation device. Without this functionality a patient programmer is not usable and cannot communicate with a neurostimulation device. (Z-2322/2323-2008) |
| Benoist-Girard | ***Hipstar V40*** Femoral Stem Howemedica | II | The warning label, "Do not use with heads more than +10 offset," does not appear on 135-degree stem boxes. This warning is contained in the instructions for use. (Z-0227-2009) |
| BioDetek | Zoll ***OneStep*** Multi-Function Electrode | II | Multifunction electrode programmed as "Pediatric" instead of "Adult." (Z-2334-2008) |
| Biogenex Labs | ***Xmatrx*** FISH | II | Bulk reagent dispensing mechanism may break, resulting in reagent spill and possible exposure to chemicals. (Z-1471-2008) |
| bioMérieux | ***BacT/Alert*** FA Culture Bottles | II | Labels contained duplicate bottle identification barcode numbers. (Z-0457-2008) |
| Biomet | ***Vanguard*** DCM CR Tibial Bearing | II | The packaging of the two products was mixed up, resulting in the products being labeled with an incorrect size. If implanted, the product may not fit properly, which could require repeat surgery. The problem could also result in a delay in the procedure. (Z-1375/1376-2008) |
| Biomet | ***Certain PreFormance*** Temporary Cylinder | III | Incorrect assembly: The product does not allow for the screw to pass through the access hole and engage the implant properly. Therefore, the provisional restoration will not be seated on the implant platform. (Z-0128-2008) |

| Manufacturer | Product | Class | Reason |
|---|---|---|---|
| Biomet | ***3i*** Locator Abutment | **III** | The locator abutment labeled as "LOA002" may contain Catalog/Item "LOA003" product, and vice versa. (Z-1363/1364-2008) |
| Biomet | ***3i Certain MicroMiniplant*** Straight Healing Abutment | **III** | The abutments do not fully seat on the restorative platform of the implant, leaving a gap between the abutment and the implant. (Z-1365-2008) |
| Biomet | EP Healing Abutment | **III** | Device packaging labeled "THA53" may contain ITHA53 devices. (Z-1366-2008) |
| Biomet | ***Navigator*** System Surgical Kit | **II** | The drill may become lodged in the handle. (Z-2199-2008) |
| Biomet | ***Optigun*** Cement Gun | **II** | A screw may come loose and fall from the device during use. (Z-0318/0319-2008) |
| Biomet | Straight Magnum Inserter Handle | **II** | The instrument was manufactured incorrectly and its use may result in binding to the acetabular component and cause the implant to not release following impaction. (Z-0115-2008) |
| Biomet | CC Cruciate Tibial Tray | **II** | Package labeled as containing a 67 mm tray actually contains a 75 mm tray, and vice versa. (Z-0706/0707-2008) |
| Biomet | ***Ringloc+*** Instrumentation Impactor Plate | **II** | The instrument will not lock onto the impactor handle; the device was distributed without assembly of the Bal Seal component. (Z-0700/0705-2008) |
| Biomet | ***Vanguard*** Width Checker and Knee Instrumentation | **II** | The instrument's sizing line is in the wrong place. (Z-1361/1362-2008) |
| Biomet | Hybrid Glenoid Boss Cutter | **II** | The glenoid implant may not seat fully on the face of the natural glenoid due to inadequate measurement tolerances in the design of the cutter. Use of the instrument may lead to incomplete seating of the glenoid implant, elevating the theoretical risk of glenoid loosening, which may lead to early revision surgery. (Z-1658-2008) |
| Biomet | Orthopedic Salvage System ***Interlok*** IM Stems | **II** | The product is not collared, although the label states that it is collared. (Z-1879/1881-2008) |
| Biomet | Orthopedic Salvage System RS Non-Modular Long Tibial Base | **II** | Product is labeled as "Reduced Size," but is actually standard size. (Z-2213/2214- 2008) |
| Biomet | ***Exact*** Calcar Planer Rasp-Style Blade | **II** | The blades will oxidize after the first cleaning. (Z-2370/2373-2008) |
| Biomet | ***Discovery*** Elbow | **II** | The component in the package is not the correct size. (Z-0032/0033-2009) |
| Biomet | Stainless Steel Crimp Sleeve | **III** | The outer package is properly labeled, but the inner package may be labeled as a femoral component. (Z-0288-2009) |
| Biomet | ***Vanguard*** DCM PS Plus Tibial Bearing | **II** | The package is properly labeled, but the laser etch for size incorrectly reads "16 X 63/63" instead of the correct size, "16 X 63/67." (Z-0289-2009) |

| Manufacturer | Product | Class | Reason |
|---|---|---|---|
| Biomet | ***Stella*** Interdental Osteotome | II | The working tips are thicker than specification. (Z-1871-2008) |
| Biomet | ***Lactosorb*** Trauma Plating System | II | The outer foil pouch on the Lactosorb Plate system was not properly sealed. The product is labeled as sterile, but the lot was not sterilized. (Z-1872-2008) |
| Biomet | ***HT X-Drive*** Screw | II | The packaging actually contained a ***Fossa X-Drive*** screw. (Z-0282-2009) |
| Biomet | ***Fredrick's*** Converse Retractor | III | Fiber optic cable is missing. (Z-0415-2009) |
| Biomet | Modular Microplasty Cup Inserter | II | The pin and clip may fracture during use. (Z-0181-2009) |
| Biomet | ***EZLoc*** Femoral Fixation | II | Devices were distributed with the incorrect component size inside the package. (Z-1782-2008) |
| Bionime | ***Invictus Rightest*** Blood Glucose Monitoring System | III | When the meter is fixed in 12-hour mode, the timeframe display of all memory data will be shown incorrectly as "AM" or "PM," depending on when the user is recalling the memory stored in the meter. This will cause confusion as to when the last test was taken. (Z-0728-2008) |
| Bio-Rad | ***Architect Free T4 MasterCheck*** | III | Testing material becomes unstable at the recommended storage temperature. (Z-1569/1570-2008) |
| Bio-Rad | Various ***Bioplex*** Devices | II | False-negative results due to reagent packs exhibiting low signal. (Z-1156/1159-2008) |
| Bio-Rad | ***Kallestad*** HEp-2 Cell Line Substrate; Kallestad Mouse Stomach/Kidney; Kallestad Mouse Kidney | III | The homogeneous positive control was released with a titer value of 1:256 rather than the titer value of 1:128 reported on the QC report label included with each test kit. (Z-2430-2008) |
| Bio-Rad | ***BioRad BioPlex 2200*** Software | II | An error in the software results in assignment values being used that may be slightly different from those printed on the "Value Assignment Data Sheet." (Z-0575-2008) |
| Bio-Rad | ***Variant*** ß-thalassemia Short Program Hemoglobin Testing System | II | Some product ROM cards have an incorrect program loaded and are unable to be updated. (Z-1588/1589-2008) |
| Bio-Rad | ***Architect LH MasterCheck*** | III | The values listed in the data sheet are incorrect. (Z-0216-2009) |
| Bio-Rad | ***Monolisa*** Anti-HBc EIA | II | Patient samples that are negative for antibodies to anti-HBc could be assigned a positive result. (Z-1189-2008) |
| BioSense Webster | Circular Mapping Catheter | II | The catheter may become caught in the mitral valve, requiring surgical procedures. Valve may be torn while trying to dislodge, unable to retract the catheter through the sheath and require surgical intervention to remove. Pulling on catheter to remove may lead to large arterial septal tear, and separation of the distal end of the catheter may occur. Also, when the catheter is fully deflected and the variable loop is fully contracted, it is possible that the catheter mechanism can become locked in position. (Z-1703/1704-2008) |

| Manufacturer | Product | Class | Reason |
|---|---|---|---|
| Biosite | ***Triage*** Micro ClostrIdium Difficile Panel | II | Toxin results have shown falsely lower visual signals in certain lots compared to results observed with previous lots. (Z-1352-2008) |
| Biotronik | ***Lumax*** Cardiac Resyncronization Therapy Defibrillator | III | An implementation error allows the usage of the "V-V" timing feature, which is not approved for use in the U.S. (Z-1373-2008) |
| Bisco | ***Biscem*** Dual-Cured Self-Adhesive Resin Cement | II | After 15 months of storage, cement used in self-cure mode only without light curing may take longer than specified to set, resulting in reduced bond strength. Product component(s) also may thicken slightly over time. (Z-1696/1697-2008) |
| B-K Medical | Intraoperative Transducer | II | Incomplete glue joint in the device housing may affect electrical safety or sterilization. (Z-1140-2008) |
| Blackstone Medical | ***Hallmark*** Anterior Cervical Plate System | II | The laser marking on the head of the screw lacked complete process qualification. (Z-0478-2008) |
| Boston Scientific | ***SteeroCath-T*** Ablation Catheter and ***SteeroCath-Dx*** Diagnostic Catheter | II | Package sterile barrier may be breached, compromising sterility. (Z-1617/1618-2008) |
| Boston Scientific | ***LeVeen SuperSlim*** Needle Electrode | II | The cannula may become detached from its correct orientation inside the handle and may prevent retraction of the tines. (Z-1913/1916-2008) |
| Boston Scientific | ***Flexima*** Biliary Stent System | III | ***Rapid Exchange*** Biliary Stent may be mislabeled as ***Flexima*** Biliary Stent, which has a different delivery system included in the package. (Z-2105-2008) |
| Boston Scientific | ***iReview*** Software for ***iLab*** Ultrasound Imaging System | II | Software was released for distribution in a non-validated format. (Z-2006-2008) |
| Boston Scientific | ***EndoVive*** Safety 24 Fr PEG Kits | III | Inner box is labeled "20 Fr PEG," but the outer and tray label is correctly labeled "24 Fr PEG." (Z-2236/2237-2008) |
| Boston Scientific | ***iLab*** Ultrasound Imaging System | II | Improperly terminated wires on a component of the processor power supply could cause the processor to lock up or stop, and prolong the patient's procedure. (Z-1693-2008) |
| Boston Scientific | ***NexStent*** Monorail Carotid Stent System | II | Tip may detach from stent delivery system. (Z-2089-2008) |
| Boston Scientific | ***Platinum Plus*** Guide Wire | II | The PTFE (polytetrafluoroethylene) coating on the guide wires could be damaged in certain locations. This damage of the coating creates the potential for small particles of the PTFE coating to detach from the wire. If PTFE particles detach from the guide wire and are released into the coronary vasculature, the particles may occlude a blood vessel. (Z-2362/2365-2008) |
| Boston Scientific | ***Platinum Plus LT*** | III | Product may be labeled as a 260 cm-long guide wire when the actual packaged device is a 180 cm-long guide wire, and the product may be labeled as a 180 cm-long guide wire when the actual packaged device is a 260 cm-long guide wire. (Z-0030/0031-2009) |

| Manufacturer | Product | Class | Reason |
|---|---|---|---|
| Boston Scientific | ***Easy Core*** Biopsy Systems | III | Difficulty cocking or arming the cannula latch on the device. This difficulty may result in an inability to use the device. (Z-0328/0337-2009) |
| Boston Scientific | ***iLab*** Ultrasound Imaging System | II | Products may be infected with a "worm," which could infect a computer network to which it may be connected. (Z-0338-2009) |
| Boston Scientific | ***Vitality DR+*** and ***EL*** Implantable Cardioverter Defibrillators | II | Repetitive mechanical stress applied to the titanium case can induce component damage and device malfunction in certain ICD and CRT-D devices implanted subpectorally with the serial number facing the ribs. (Z-1513/1514-2008) |
| Boston Scientific | ***NexStent*** Monorail | I | Detachment of the tip from the ***NexStent*** delivery system. (Z-2141-2008) |
| Boston Scientific | ***Scimed Maverick 2*** Monorail PTCA Catheter | II | The units within this lot may not meet thickness specifications surrounding the wire exit port wall, which may result in an air embolization if the port septum wall bursts. (Z-2165-2008) |
| Boston Scientific | ***Scimed Maverick 2*** Monorail Balloon Catheter | II | Two lots may not be correctly labeled. Specifically, a 2.5 mm x 12 mm unit was incorrectly labeled as a "3.5 x 20 mm" unit on the box and Tyvek label. (Z-2166-2008) |
| Boston Scientific | ***Smash*** Balloon Dilatation Catheter | II | There is an increasing trend in complaints regarding cracks and damage to the balloon inflation hub. The potential clinical effects related to these types of cracks and damage could include no inflation, difficulty inflating, slow deflation, partial deflation or – in a worst case scenario – no deflation of the balloon. (Z-1652-2008) |
| Boston Scientific | ***LeVeen SuperSlim*** Needle Electrodes | II | The cannula may become detached from its correct orientation inside the handle and may prevent retraction of the tines. (Z-2091/2094-2008) |
| Boston Scientific | ***FilterWire EZ*** Embolic Protection System | II | The directions for use may be missing. (Z-0105/0110-2009) |
| Byron Medical | Various Tubing | II | During packaging integrity validation, it was found that various product packages could fail, compromising the sterility of the devices. (Z-1790/1799-2008) |
| C&A Tool Engineering | Modular Microplasty Cup Inserter | II | The weld at the lock location may fracture during impaction. (Z-1185/1187-2008) |
| CP Medical | Various Fiducial Markers | III | Markers were incorrectly labeled as soft-tissue gold markers, but packages contained bone gold markers. (Z-1613/1614-2008) |
| Caire | Generation 4 Electronic Liquid Gauges | II | Moisture ingress into the electronic liquid-level indicator may cause inaccurate liquid-oxygen-level readings. The oxygen could run out without the patient knowledge. (Z-1716-2008) |
| California Medical Labs | ***CalMed*** Pericardial Sump | II | The product may have a loose, stainless-steel stringer flash located at the distal tip of the product. (Z-1175/1177-2008) |
| Cardiac Science | 9051 Electrode Adapter | III | The red and white connector ends of the adapter are switched. Therefore, the cable will not connect to the electrodes as indicated in the instructions. (Z-1616-2008) |
| Cardiac Science | Electrode Adaptor Cable Quick-Combo System | II | Instructions are not clear about how the AED voice and text prompts will differ when the adapter is used. (Z-1714-2008) |

| Manufacturer | Product | Class | Reason |
|---|---|---|---|
| Cardinal Health | ***AirLife*** Infant nCPAP System Driver | II | The system exhibited $O_2$ fluctuations when used with low $O_2$ flow rates when the PTO/Auxiliary port on the driver is used as a blender in administering $O_2$ therapy via nasal cannula at flow rates of less than 4L/min. (Z-0987-2008) |
| Cardinal Health | Various Pulmonetic Systems LTV Ventilators and Replacement Kits | II | The failure of an electronic component could result in failure of the ventilator to breathe for the patient and/or failure of the ventilator to properly alarm to alert the caregiver. (Z-1463/1470-2008) |
| Cardinal Health | U19 Socketed Integrated Circuit; Grey Inter-Unit Interface Connectors; U9 Socket Integrated Circuit | II | A channel error will stop an active infusion (or monitoring) with an audible and visual alarm. (Z-1710/1712-2008) |
| Cardinal Health | ***Alaris*** Pump Module | I | Inaccurate flow rate related to misassembled (missing, bent or broken) springs during the manufacturing or servicing of the mechanism assembly. (Z-0460-2008) |
| Cardinal Health | GSI Audera | II | Requires a system software update due to issues with the "Split-Screen" and the "Vestibular Evoked Myogenic Potential" functions. (Z-0195-2009) |
| Cardinal Health | ***NicoletOne*** Photic Adapter Cable | II | The photic adapter cable has a wiring error, which delivers a reduced voltage and results in a decreased intensity of the ***NicLED*** photic. This reduced intensity may fail to elicit a response from a photosensitive seizure disorder patient. (Z-2389-2008) |
| Cardinal Health | ***NicoletOne*** Software | II | The third-party room relay connected to the A2 wall plate does not always activate if the patient event button connected to the ***CSeries*** Amplifier is pressed twice within one second. (Z-2459-2008) |
| CAS Medical Systems | ***740 Series*** Multiparameter Monitor | II | Audible alarm may be silenced if changed from the factory setting. (Z-2203-2008) |
| Celsus Labs | Heparin Lithium Lyophilized | II | Up to 2.2% oversulfated chondroitin was found in a batch of crude heparin received from a supplier. (Z-1917-2008) |
| Cepheid | ***Xpert GBS*** Assay Diagnostic Test Kit | III | Some cartridges may be mislabeled as "Xpert EV" instead of "Xpert GBS." (Z-0376-2008) |
| Chattanooga | Various ***Intelect*** and ***Vectra*** Devices | II | Device malfunctions, causing electric shock and burn. (Z-1218/1232-2008) |
| Chattanooga | Various ***Intelect*** and ***Vectra*** Devices | II | Device may fail to administer therapy during use. (Z-1636/1638-2008.) |
| Chiu Technical | Transilluminator | II | Device was marketed without FDA 510(k) clearance. (Z-0320-2008) |
| Cholestech | ***Cholestech LDX*** High Sensitivity C-Reactive Protein Test Cassette | III | Test results are high, outside of control material upper-limit specification. Results could be as high as 15%. (Z-2457-2008) |
| Civco Medical Instruments | Latex-Free Needle Guide | III | The individual pouches contained V53W endocavity needle guide instead of the Shimadzu T/R needle guide. (Z-1054-2008) |
| Clinical Innovations | ***ClearView*** Uterine Manipulators | II | Inadequate package seal could compromise sterility. (Z-1817/1818-2008) |

| Manufacturer | Product | Class | Reason |
|---|---|---|---|
| Coloplast Manufacturing | ***Elefant*** Suction/Irrigation Cannulas and Tubing | II | Sterilization of devices is not performed according to ISO 11135 standard. (Z-0713/0715-2008) |
| Community Products | Toddler Chair Hip Strap | III | Some hip straps were assembled incorrectly by threading the buckle on the strap upside down. A defective hip strap could loosen, allowing the child to slip down in the chair and this could create a choking hazard. (Z-0318-2009) |
| ConMed | ***VCARE*** | II | There is a detachment of the balloon at the distal end of the shaft. Also, the incidence of the forward cup slipping off the shaft and being retained in the vaginal canal had increased. (Z-0175/0180-2009) |
| ConMed | ***Linvatec*** Surgical Video Cart | II | There is a possibility the wheel caster(s) may become loose. (Z-2458-2008) |
| Connectorate | Heparin Adsorbent | II | Erroneous coagulation tests. (Z-0934-2008) |
| Contour Fabricators | Vascular Drape, Surgical Drape and Drape Accessories | II | Product does not have FDA 510(k) approval for use. (Z-1372-2008) |
| Contract Medical Manufacturing | Custom Cranial Implant Kit | I | Lack of assurance of sterility. (Z-0509/0512-2009) |
| Convatec | ***GentleTouch*** System-Colostomy/Ileostomy Postoperative Kit; Ostomy Pouch and Accessories | III | The carton label reads "For post-surgical use following a urostomy procedure." It should read, "For post-surgical use following a colostomy or ileostomy procedure. (Z-1314-2008) |
| Convertors De Mexico | Presource Standard Sterile OR Scissors | II | The product has the potential of being non-sterile. (Z-1178-2008) |
| Cook | ***Cotton-Leung*** Biliary Stent | II | The product packaging label indicates the stent is 5 cm, but the actual stent inside the packaging measures 10 cm. (Z-2331/2332-2008) |
| Cook | ***Zilver*** Expandable Metal Biliary Stent System | II | A section of the introduction system may detach after the stent has deployed. (Z-0113-2009) |
| Cook | Vascular Wire Guide | II | The device was not sterilized and is not adequately labeled. (Z-0135-2008) |
| Cook | Peel-Away Introducer Set | II | The peel-away sheath does not peel uniformly or completely. (Z-0892/0904-2008) |
| Cook | ***Hilal*** Embolization Microcoils | III | The product length is declared incorrectly in millimeters, when the unit of measurement should be in centimeters. (Z-2057/2058-2008) |
| Cook | ***Flexipet*** Manipulation Pipette | II | 300-micron flexipets were labeled as "80 microns." (Z-2178-2008) |
| Cook | Vital Port Vascular Access System Polysulfone Petite | II | Wrong size catheter was packaged in the box. (Z-2190/2191-2008) |

| Manufacturer | Product | Class | Reason |
|---|---|---|---|
| Cook | ***Flexipet*** Denuding Pipettes | II | 300-micron flexipets labeled as "130 micron," and vice versa. (Z-2176/2177-2008) |
| Cooper Surgical | M-Style Mushroom Cup Vacuum-Assisted Delivery System; M-Style Cup with Universal Vacuum Release; ***Mystic II*** M-Style Mushroom Cup Vacuum-Assisted Delivery System | II | System may have a loss of vacuum, or the cup will not release from the baby's head. (Z-1887/1889-2008) |
| Cordis | ***S.M.A.R.T.*** Control Nitinol Stent System | II | The device was manufactured with a prior version of the guide wire lumen material, which is not validated with the current manufacturing process. This condition may result in a separation of the device. (Z-1556-2008) |
| Cordis | ***Dura Star*** and ***Fire Star*** Dilatation Catheters | I | Slow deflation or no deflation. (Z-0747/0824-2008) |
| Cordis | ***Outback LTD*** Re-Entry Catheter | II | The separation rate of the cannula to the deployment slide of the handle assembly is higher than anticipated. The cannula is unable to be retracted into the device after deployment due to a separation of the inner key from the cannula. (Z-0279-2009) |
| Covidien | Heparin Lock Flush Syringes | II | Syringes contained a heparin-like contaminant. (Z-1594/1602-2008) |
| Covidien | ***ReliOn*** Insulin Syringes | I | Package labeled as an insulin syringe for use with U-100 insulin contains an insulin syringe for use with U-40 insulin. (Z-0284-2009) |
| Covidien | ***Palindrome*** Emerald Sport Pack Cuffed Dual Lumen Catheter with Pre-curved Shaft and Heparin Coating | III | Incorrect size of the ***Venetrac*** stylets (an optional accessory). They are too short and cannot be used. (Z-0408/0411-2009) |
| CryoLife | ***CryoValve*** Aortic Valve & Conduit, and Pulmonary Valve & Conduit | II | Tissues taken from a donor whose blood culture was found positive for *Serratia marcescens*, was distributed. (Z-1523/1524-2008) |
| CTS | ***Vasoview 4*** Endoscopic Vessel Harvesting System | II | Sterility of product may be compromised due to packaging issue. (Z-0476-2009) |
| Curlin Medical | Various Ambulatory Infusion Pumps | II | The pumping chamber door (platen) had become deformed in a manner that permitted gravity flow. (Z-1896/1900-2008) |
| Custom Ultrasonics | ***System 83*** Plus Washer-Disinfector | II | Inadvertent selection of the "wash" cycle. (Z-1182-2008) |
| Cyberonics | ***VNS*** Therapy System Model 250 Handheld Programming System | III | The Dell ***X5*** Handheld PC screen will freeze due to incompatibility between the Microsoft 2002 operating system and the X5 handheld computer. Once frozen, the handheld device becomes non-responsive to user input. (Z-0568-2008) |

| Manufacturer | Product | Class | Reason |
|---|---|---|---|
| Dade Behring | ***Dimension*** Enzymatic Creatinine Flex Reagent Cartridge | II | Reagent may exhibit unflagged, inaccurate patient sample results. (Z-0485-2009) |
| Dale Medical Products | Dale Trachestomy Tube Holders | II | Labeling was revised to read, "Do not trim fastener hook tabs." Trimming can cause tabs to disengage at the trach plate. (Z-0446/0447-2008) |
| Datascope | ***Panorama*** Patient Monitoring Network; ***Panorma Telepack*** 608 | II | If an ECG cable, which has been damaged due to the ingress of liquid or by mechanical trauma, is utilized with the ***Telepack***, it may cause the Telepack to switch between the 3-lead and 5-lead-input modes. During the switching process, the digital heart rate displayed at the ***Panorama*** Central Station will be frozen, and subsequent arrthymia alarms will not be announced. (Z-0150-2008) |
| Datascope | ***CS 100*** and ***CS 300*** Intra-Aortic Balloon Pumps | II | A defect in the printed circuit boards may cause the pump to exhibit intermittent malfunctions, which include failure to start up, or reset of the display screen during therapy. (Z-0567-2008) |
| Datex-Ohmeda | ***Engstrom*** Carestation | II | There is an issue relating to the removal of the nebulizer cable from nebulizer connection port, which, when done while the nebulizer is active, may result in the discontinuance of mechanical ventilation. (Z-1829-2008) |
| Datex-Ohmeda | ***Corometrics*** Maternal/Fetal Monitor | II | Communication connector within the monitor is defective and may cause potential loss of telemetry. (Z-2154-2008) |
| Datex-Ohmeda | ***Giraffe OmniBed*** | II | The device labeling was changed to account for new use and care instructions. (Z-0305-2009) |
| Datex-Ohmeda | ***Panda iRes*** and ***Giraffe*** Infant Warmers | II | Medical device software may be subject to signal interference of the hands-free alarm silence feature, which could impact patient safety. (Z-2227-2008) |
| Datex-Ohmeda | ***Aisys*** | II | The electronic vaporization system in the ***Aisys*** anesthesia machine contains a backpressure valve, inflow check valve and cassette interface board, which can contribute to independent failures. (Z-0020-2009) |
| DePuy | ***TK2*** Compression Hip Screw Trauma Plate | II | The lot with the short barrel was etched and labeled as a standard barrel, and the lot with the standard barrel was etched and labeled as a short barrel. (Z-0434/0435-2008) |
| DePuy | ***LCS*** Orthopedic Knee Implant | II | Inserts were labeled and packaged as "Size Standard, 12.5 mm Inserts," but were actually 10 mm inserts. (Z-1812-2008) |
| DeRoyal Lafollette | Lap Appy ***TraceCart*** and Lap Chole Tray | II | Surgical kits contained recalled ***Endopath ETX*** 35 mm Endoscopic Linear Cutter White Reload/Cartridges. (Z-0197/0198-2009) |
| DiaDexus | PLAC Test Reagent Kit | II | Product may give Lp-PLA2 values at up to 22% lower than accurate values. (Z-2399/2400-2008) |
| Diagnostica Stago | ***STA*** Neoplastine CI 10; ***STA*** Neoplastine CI Plus 10 | II | There is the potential for a lack of homogeneity between product vials. (Z-0501/0502-2009) |
| Diasorin | ***Liason*** 25-OH Vitamin D Kit | III | Kits may sporadically recover kit and external control values out-of-range high. (Z-1240-2008) |

| Manufacturer | Product | Class | Reason |
|---|---|---|---|
| Difco Labs | FA *Streptococcus* Group A | III | The product exhibited decreased fluorescence when testing with the homologous control organism. (Z-1319-2008) |
| Donatelle | ***Attain LDS*** 6216A; ***Attain Access*** 6218A | II | Valve package seals could be compromised. (Z-2471/2473-2008) |
| Draeger | Various ***Evita*** Critical Care Ventilators | II | Audible power failure alarm was not enunciated at the required volume. (Z-2325/2327-2008) |
| Draeger | ***Fabius*** Trio Gas Machine | II | The lower side rail of the frame of the machine may break inwards when being moved across a threshold, resulting in the machine being unstable. (Z-2338-2008) |
| Draeger | ***Apollo*** Anesthesia Machine | II | Sporadic errors in various device functions, including low readings of the single-gas flows for oxygen, nitrous oxide, or air delivery, or mechanical ventilation failure. (Z-0087-2009) |
| Draeger | ***Fabius GS*** Anesthesia Machine | II | The caster may break loose from the chassis. (Z-1315-2008) |
| Draeger | ***Oxylog 3000*** Emergency and Transport Ventilator Continuous Respirator | II | May experience an interruption of ventilation for approximately five seconds. (Z-0202-2009) |
| Draeger | ***TI500***, ***GT500*** and ***Globe Trotter IC*** | II | The power board, which controls the incubator heater, may not regulate the temperature properly, resulting in a high temperature alarm and a loss of temperature control within the patient compartment. (Z-1051/1053-2008) |
| Drummond Scientific | Various ***SafeCrit*** and ***ClearCRIT*** Tubes | II | Presence of oversulphated chondroitin sulphate contaminant. (Z-0208/0211-2009) |
| Drummond Scientific | ***StatSampler*** | II | Ethylenediaminetetraacetic acid was inadvertently mixed with lithium heparin solution contained in capillary tubes. (Z-2234-2008) |
| D-Tek | Is-anti-Gliadin IgG Enzyme Immunoassay Test Kit | II | Standards and controls in the Is-anti-Gliadin IgG Test Kits are exhibiting low activity. (Z-1684-2008) |
| Eagle Medical | Smooth or Threaded Metallic Bone Fixation Fastener Locking Cortical Screw | III | The inner sticky labels for the patient identified the product incorrectly as a cortical screw (non-locking). (Z-2135-2008) |
| EBI | ***InterGro DBM*** Demineralized Bone Matrix In A Lipid Carrier | II | Product was not stored under controlled conditions and may have been temperature abused. (Z-2351-2008) |
| EBI | Trauma Fixation Systems Slotted Mallet | II | The mallet handle may separate during a medical procedure. (Z-2012-2008) |
| Edwards LifeSciences | ***FlexStar*** Biliary Stent System | II | Products were labeled with an incorrect shelf-life expiration date. Therefore, the sterility of the device may be compromised. (Z-1246/1296-2008) |
| Edwards LifeSciences | ***Fem-Flex II*** Cannulas and Catheters | II | Femoral venous cannula was color-coded as an arterial cannula. (Z-1893/1894-2008) |

| Manufacturer | Product | Class | Reason |
|---|---|---|---|
| Edwards LifeSciences | ***Thin-Flex*** Venous Return Cannula | III | Reinforcement spring may detach from the cannula body, resulting in reduced venous blood-return flow. (Z-2401/2403-2008) |
| Edwards LifeSciences | ***Fogarty Fortis*** Arterial Embolectomy Catheter | II | Potential for tubing fracture near the tip of the catheter. (Z-0013-2009) |
| Edwards LifeSciences | ***LifeStent FlexStar*** Self-Expanding Biliary Stent System | II | There may be a gap between the tip of the delivery system and the primary sheath. (Z-0035/0085-2009) |
| Ekos | ***EndoWave*** Infusion System | II | The 6 cm treatment zone catheter was built using 50 cm treatment zone drilled tubing. (Z-1892-2008) |
| Ekos | ***EndoWave*** Infusion System | II | There is a potential for the catheter to disconnect from the catheter interface cable pod that connects to the control unit. (Z-1773-2008) |
| Ekos | PT-3B Control Unit | II | There is the potential for the unit to burn the patient. (Z-1752-2008) |
| Ellex Medical | ***Eye Cubed*** Ultrasound | II | Incorrect IOL calculations may occur. (Z-0148-2008) |
| Emageon | ***Enterprise*** Visual Medical System | III | The calculation of the standard uptake value does not include the required calibration factor/decay correction factor. (Z-1644-2008) |
| EMD Chemicals | Harleco Ethanol Standard | III | Two ampules measuring 2.0 mg/ml were found in a lot of 20 ampules of 1.0 mg/ml ethanol standard. (Z-1607-2008) |
| EMD Chemicals | Histochemical Periodic Acid Schiff Reaction Set | III | The kit was not performing properly with positive controls. (Z-2303-2008) |
| EMG Technology | ***Medline EndurO$_2$*** Oxygen Concentrator with Oxygen Monitor | II | There is the potential for an electrical component in the oxygen concentrator to overheat, causing damage to the unit and making it nonfunctional. (Z-1473/1474-2008) |
| Encore Medical | ***Keramos*** Replacement Polyethylene Liner | II | The polyethylene liner was used as a replacement for the ***Keramos*** ceramic liner in revision hip replacement surgeries without FDA 510(k) approval. (Z-1785-2008) |
| Encore Medical | Foundation Knee System Tibial Fixed Impactor | II | There was a fracture of the Nitronic 60 screw on the tibial fixed impactor during surgery. (Z-2466-2008) |
| Encore Medical | ***VariLift*** Bone Plug with End Cap | II | The device was marketed without the label warning required in the device's 510(k) approval letter. (Z-0306/0311-2008) |
| Encore Medical | ***3DKnee*** Tibial Insert Trial | II | The device thickness was marked correctly as "13 mm" on the underside of the trial, but is incorrectly marked as "15 mm" on the side. (Z-1539-2008) |
| Enterix | ***Insure Quik Fit*** Developer Kit | II | Reduced sensitivity could affect the test line area and/or control line on the test strips, which may lead to inaccurate results. (Z-0480-2009) |
| Ethicon | ***Endopath*** Curved Dissector with Monopolar Cautery | II | Damaged packaging may have compromised the sterility of the devices. (Z-0565-2008) |
| Ethicon | Vicryl Rapide Braided Coated Synthetic Absorbable Suture | II | Package defect compromised the integrity of the primary seal, which could lead to premature suture degradation and/or impair the sterile barrier of the product. (Z-0021-2009) |

| Manufacturer | Product | Class | Reason |
|---|---|---|---|
| Ethicon | ***Endopath*** Endoscopic Linear Cutters; ***FlexTray*** Procedure Delivery System | II | The firm discovered a component production issue, which may cause the cartridge to deploy an incomplete staple line. (Z-2160/2164-2008) |
| Ethicon | Lupine BR Anchor | II | The suture loop was not assembled at the distal end of the anchor. (Z-1810-2008) |
| Ev3 | ***Protégé*** GPS Biliary Stent Systems | II | Device mislabeling resulted in a 9 mm diameter, 60 mm length stent being labeled as a "6 mm x 60 mm" stent. (Z-2169-2008) |
| Ev3 | ***Primus*** GPS Biliary Stent Systems | II | Device mislabeling resulted in a 8 mm diameter, 27 mm length stent being labeled as a "8 mm x 37 mm" stent. (Z-2170-2008) |
| Ev3 | ***IntraCoil*** Self-Expanding Peripheral Stent | III | The 5 mm x 40 mm stent was labeled as a "5 mm x 60 mm" stent. (Z-1815-2008) |
| Ev3 | ***Visi-Pro*** Balloon-Expandable Peripheral Stent and Biliary Stent Systems | II | System may not have adequate securement of the stent to the delivery system and may have a larger diameter/profile than intended. (Z-1547/1548-2008) |
| Ev3 | ***IntraCoil*** Self-Expanding Peripheral Stent | III | A 6 mm x 40 mm stent was labeled as a "6 mm x 60 mm" stent. (Z-1816-2008) |
| Exactech | ***Biolox Alu***mina Femoral Head Hip Prosthesis Component | III | Femoral heads were incorrectly labeled as "140-28-03 12/14 ***Biolox*** Forte Alumina Femoral Heads, 28mm." (Z-0572-2008) |
| Exocomm Tech Group | ***Life+Cel*** Replacement Battery | II | Marketed without FDA 510(k) clearance. (Z-0521/0522-2008) |
| Extron Electronics | OEM, CAB, DVI-Male to DVI-Female Cable Assembly | III | Cables causing intermittent or complete loss of signal on monitors used in surgery. (Z-0302/0303-2008) |
| Facet Technologies | ***Premier*** Value Lancing Device | II | The alternate site cap was not included in the package, as indicated on the labeling. (Z-0174-2009) |
| Ferno-Washington | Mobile Transporters | II | Some corner castings on the stretchers were oversized. (Z-1859-2008) |
| Ferno-Washington | ***PROFlexX*** Ambulance Stretcher | II | Device legs could experience metal fatigue and possibly fracture after one to two years of use, based on the usage and method of operation. (Z-2465-2008) |
| Fertility Technology Resources | Various ***Tucker*** Embryo Catheters | II | The five-year dating could not be validated/supported for sterility assurance. (Z-0662/0667-2008) |
| FHC | ***MicroTargeting*** Electrodes and Kits | II | Package may contain an electrode longer than the labeled size. (Z-0497/0498-2009) |
| FHC | ***MicroTargeting*** Platform DBS Measuring Fixture | II | Measuring fixture is incorrectly graduated. (Z-0486-2009) |
| First Aid Only | First Aid Kits | III | Device failed its USP limits for impurities during stability testing. (Z-0853/0855-2008) |

| Manufacturer | Product | Class | Reason |
|---|---|---|---|
| Fisher & Paykel Electronics | RT240 Adult Breathing Circuit Kit | II | Kits included a heated breathing circuit that may be more susceptible to damage when used in excess of the specified seven-day maximum duration of use, which may increase the risk of malfunction or fire. (Z-0414-2009) |
| Focus Diagnostics | ***HerpeSelect*** Immunoblot IgG Kits | II | In a small percentage of samples tested in specific lots, the HSV common antigen band appears lighter (less reactive) than the reading control band. (Z-1764-2008) |
| Fresenius Medical Care | ***Optiflux*** 180NR Advanced Fresenius Polysulfone | II | The dialyzer may leak at the header, resulting in small amounts of blood loss. (Z-0738-2008) |
| Galil Medical | Urethral Warming System | II | The warming catheter was manufactured with the inlet and outlet tubes switched. (Z-1698-2008) |
| Gambro | Cartridge Blood Set with ***Phoenix*** Hemodialysis System | II | Improper tubing installation may result in serious injury or death. (Z-1367-2008) |
| Gambro | Cartridge Blood Set | II | Dialysis tubing sets may have occlusions restricting blood flow. (Z-1860/1861-2008) |
| Gauthier Biomedical | ***Comfort*** T-Handle Hudson Connector with Impactor Cap | II | The collar spring binding on the shaft of the generic handle used with multiple surgical instruments has the potential to release the device's internal bearings during use. (Z-0880-2008) |
| Gebauer | Fluoro-Ethyl Nonflammable Topical Anesthetic Skin Refrigerant | II | Device may contain a defective valve that could malfunction and spray refrigerant out from the side of the valve. (Z-0218-2009) |
| General Electric | ***Proteus XR/a*** Radiographic System | II | The warning label that is required by 21 CFR 1020.30(j) was not on the control console. (Z-0842-2008) |
| General Electric | ***Precision 500D*** Classical R&F System with Control Room PC | II | Inaccurate cassette size display reading/inaccurate mAs reading. (Z-0274-2008) |
| General Electric | ***Precision 500D*** Classical Radiographic-Fluoroscopic X-ray System | II | When the foot pedal is repeatedly activated, a defect in the fluoro-timer will cause the dose measurement to report a higher value than was actually received by the patient. (Z-0369-2008) |
| General Electric | Various ***Signa*** MR Systems | II | An artifact could affect the diagnostic capability. (Z-1890/1891-2008) |
| General Electric | ***Definium 8000***; ***Precision 500D*** | II | Necessary certification labels are missing from the X-ray control. (Z-1476/1477-2008) |
| General Electric | ***Definium 8000*** Digital Radiographic System | II | A software anomaly may impact patient safety when using the "VolumeRAD" advanced application. (Z-1822-2008) |
| General Electric | ***Definium 8000*** Digital Radiographic System. | II | Occasional generator software errors may cause light X-ray images with reported mAs readings higher than was actually exposed to the patient using the overhead X-ray tube. (Z-1882-2008) |
| General Electric | ***Precision 500D***; ***Advantx Legacy*** Radiographic and Fluoroscopic Systems | II | X-ray production was possible from the fluoroscopic X-ray tube when the primary protective barrier was not in position to intercept the X-ray beam. (Z-1610/1611-2008) |

| Manufacturer | Product | Class | Reason |
|---|---|---|---|
| General Electric | ***Proteus XR/a Eclipse*** Collimator | II | The actual average illuminance for the collimators is approximately 140-lux. This does not meet the 160-lux requirement. (Z-1713-2008) |
| General Electric | ***Definium 8000*** Digital Radiographic System | II | The manual switch for disabling positive beam limitation was not properly labeled. (Z-1883-2008) |
| General Electric | Monitor Suspensions Used with ***Advantx*** Legacy | II | Suspensions did not have the required thread locking agent applied to the setscrew, allowing the setscrew to back out over time, which can lead to the monitor dropping. (Z-0200-2009) |
| General Electric | ***S/5 iCentral*** | II | An active monitor could become disconnected from the unit without any notification or alarm. (Z-1161-2008) |
| General Electric | ***Centricity*** PACS RA1000 Workstation | II | Four special characters, when entered into the exam notes, are not transferred to the preview panel or hard copy printout. (Z-1104-2008) |
| General Electric | ***Centricity*** Perinatal System | II | When the "PFILS" application experiences a network interruption, it could result in the ***Centricity*** Perinatal application recording non-identifiable patient information to the incorrect patient file. (Z-2037-2008) |
| General Electric | ***Centricity*** AW Software | II | Incorrect measurement of the aortic length in certain cases of aneurysm during the use of the "Aorta Protocol" or "Customized Protocol." (Z-1825-2008) |
| General Electric | ***Centricity*** PACS RA1000 Workstation | II | A software anomaly results in an incorrect study date and time information being displayed in the report screen and title, which may result in a potential patient misdiagnosis. (Z-1826-2008) |
| General Electric | ***Centricity*** AW Suite Software | II | The software may reload saved tracking objects incorrectly and display an incorrect vessel label over the restored images. (Z-2183-2008) |
| General Electric | ***Centricity*** Perinatal System | II | On the "I&O" chart, the "IN," "OUT" and "NET" fluid totals values will not honor the numeric precision configuration. (Z-0112-2009) |
| General Electric | ***Centricity*** Perinatal System | II | When attempting to select the last visible alert or reminder choice, the next choice on the list below the desired choice is selected, and an inconsistent color may be displayed for the same clinical element across a set of work stations. (Z-0456-2009) |
| General Electric | ***Centricity*** PACS RA1000 Workstation | II | Software anomalies result in patient safety issues involving patient jacket content intermittently becoming unintentionally out of synchronization with the images being displayed. (Z-0460-2009) |
| General Electric | Various ***Innova*** Cardiovascular Imaging Systems | II | During an acquisition ("fluoro" and/or "record"), an image may become "frozen" on the digital leader acquisition system live monitor screen. (Z-0690/0692- 2008) |
| General Electric | ***DST-XL*** Multi-Head Whole Body Gamma Camera | II | A cable failure associated with the arm or gantry rotation of the camera may impact patient safety. (Z-2008-2008) |
| General Electric | ***Advantx-E*** and ***Innova*** Devices | II | Risk of sudden table drop. (Z-2038/2043-2008) |
| General Electric | ***Innova 3100*** Digital Fluoroscopic Imaging System | II | Incorrect dose data After 6 days and 4 hours without performing a system reset or a system reboot, the displayed dose data on these systems may be underestimated by up to 50%. (Z-1516/1517-2008) |

| Manufacturer | Product | Class | Reason |
|---|---|---|---|
| General Electric | Various ***Innova*** Imaging Systems | II | Due to insufficient securing of the connecting elements, the LCD vertical monitor support may disengage from its arm and fall on the table or into the table vicinity. (Z-2356/2361-2008) |
| General Electric | ***Innova 3100*** and ***4100*** Digital Fluoroscopic Imaging Systems | II | Users may be unable to terminate X-ray exposure after releasing the hand-switch control. (Z-1521/1522-2008) |
| General Electric | ***Stereotaxy*** Positioner | II | There may be an X-ray emission beyond the edge of the detector primary barrier. (Z-2146/2147-2008) |
| General Electric | ***Advantage*** Workstation | II | A possible mismatch between the label of the tracked vessel and the underlying image associated with the cardiovascular applications of the workstation may impact patient safety. (Z-2312-2008) |
| General Electric | ***Innova*** Cardiovascular Imaging Systems | II | The charger and/or battery of the may fail earlier than expected with no advance warning, causing the system to shut down. (Z-2435/2438-2008) |
| General Electric | ***Voluson E8*** Ultrasound System | II | There may be potential inaccuracies of fetal cardiac measurements that may impact patient safety. (Z-2404-2008) |
| General Electric | Various ***Innova*** Digital Fluoroscopic Imaging Systems | II | Users may be unable to hear the 5-minute fluoroscopy warning signal from the table control interface. (Z-1518/1520-2008) |
| General Electric | ***Signa HDx*** MR System | II | Signal homogeneity may be affected when "Bravo" applications are set with "IR Prep" off. (Z-2225-2008) |
| General Electric | Various ***Signa HDx*** MR Systems | II | A software issue may result in the mis-registration of functional and anatomical images. (Z-2210/2211-2008) |
| General Electric | Mobile Fluoroscopy X-ray Systems | II | Device may allow unwanted X-ray exposure to the operator. (Z-0716/0717-2008) |
| General Electric | Clinical Information Center Systems | II | There is a potential for loss of audible alarming and ECG tab-setting changes. (Z-0519-2008) |
| General Medical Merate | Various ***Precision*** X-ray Systems | II | Joystick became stuck in the Trendelenburg direction, causing the patient to slide off the table. (Z-1563/1565-2008) |
| General Medical Merate | ***Precision RXi*** Digital Remote X-ray Imaging R&F System | II | The collimator did not contain a label identifying the device as being certified to comply with applicable requirements of the X-ray performance standard. (Z-2145-2008) |
| Genzyme | ***Seprafilm*** Adhesion Barrier | II | Device sterility may be compromised. (Z-1647/1648-2008) |
| Genzyme | Equal Diagnostics Lipase Color Reagent Kit | III | The calibration and quality control is outside of the established range. (Z-2148/2151-2008) |
| Given Imaging | Diagnostic System with ***PillCam SB*** Capsule | II | The cards included in the education kit were printed incorrectly. (Z-1447-2008) |
| GMP Companies/ LifeSync | ***LeadWear*** | II | There may be intermittent failure when using LS-202 and LS-203 ***LeadWear*** in conjunction with LS-41245 and LS-41285 adaptors. (Z-1659/1660-2008) |
| Greiner Bio-One | Plastic Cannula Holdex | II | At removal of the tube from the holder, the needle may dislodge and become stuck in the tube stopper with the blunt end of the needle facing out. (Z-2134-2008) |

| Manufacturer | Product | Class | Reason |
|---|---|---|---|
| Greiner Bio-One | Plastic Cannula Holdex Tube Holder | II | At removal of the tube from the holder, the needle may dislodge and become stuck in the tube stopper with the blunt end of the needle facing out. (Z-2198-2008) |
| Greiner Bio-One | ***Vacuette*** Lithium Heparin Venous Blood Collection Tubes | III | Incorrect tube label reads, "Z Serum Clot Activator" instead of "LH Lithium Heparin" tube. (Z-0215-2009) |
| Gyrus Medical | Dissector ***PlasmaKnife*** | II | Sterility may be compromised. (Z-0273-2009) |
| Hach | ***SteriChek*** Sensitive Total Chloramines and Residual Chlorine Reagent Strips; RPC ***E-Z Chek*** Sensitive Total Chlorine and Chloramines Test Strips | II | Inconsistencies in total-chlorine and free-chlorine levels may result in providing inaccurate false-positive or false-negative results. (Z-2352/2355-2008) |
| Haeng Lim Seo Won | Acupuncture Needles | II | Marketed without FDA 510(k) clearance. (Z-0566-2008) |
| Hamilton Bonaduz | Sample Carriers for the ML Star Line | II | Product has the wrong barcode labeling. (Z-0718-2008) |
| Hamilton | Soft Grip Pipettes | II | Manufacturing issue with spring may restrict product to drawing less than half of its stated measured capacity. (Z-2232/2233-2008) |
| Hansen Medical | ***Artisan*** Control Catheter | II | The catheter's flexible bellows portion may develop a leak. This has the potential to cause loss of homeostasis, flush fluid leakage, and/or introduction of air into the catheter with a risk of subsequent embolism. (Z-2106-2008) |
| HeartLab | Cardiovascular ***DICOM Store*** | II | The electrocardiogram data of one patient is misidentified as the data of another patient. (Z-1241-2008) |
| HeartLab | Cardiovascular Results Management Product | II | Erroneous echocardiographic measurement values due to mathematical formula being mis-configured. (Z-1242-2008) |
| Hill-Rom | ***Affinity*** Birthing Bed | II | Amputation of a finger could result if a finger is placed into the opening, as the hole/opening creates a shear point when the mechanism is activated. (Z-0581/0584-2008) |
| Hill-Rom | ***Affinity 4*** Birthing Bed | II | The brakes may not hold or lock properly. (Z-0617-2008) |
| Hill-Rom | ***Century+*** Bed Siderail Upgrade Kits | II | A risk of entrapment will exist between the head and foot rails if installation instructions are followed. (Z-1777-2008) |
| Hill-Rom | 100 Low Bed | II | The upper deck may collapse to its lowest position and the caster brakes may fracture if the bed is moved while the brakes are locked. (Z-1603-2008) |
| Hill-Rom | Procedural Stretcher | III | The auto contour function on/off handle may be inadvertently activated while the head of the stretcher is raised, increasing the possibility of the head section to become jammed and preventing it from lowering. (Z-1655-2008) |
| Hill-Rom | ***Envision E700*** Low Airloss Therapy Surface | II | A defect in the software of the device may not allow the patient bed exam alarm or the patient movement alarm to function correctly. (Z-0088-2009) |

| Manufacturer | Product | Class | Reason |
|---|---|---|---|
| Hitachi | ***Cobas 6000*** Clinical Chemistry Analyzer | II | CRP assays may be calculated using incorrect calibration parameters, which could result in falsely high or falsely low patient results being reported. (Z-0576-2008) |
| Hitachi | Modular Analytics Systems | II | Possible mismatch between patient and result. (Z-0866/0870-2008) |
| Hitachi | Modular E Module Immunoassay Analyzer | II | A software bug may result in pipetting from an incorrect reagent pack and/or assigning calibration curve parameters incorrectly. (Z-0165-2009) |
| Hitachi | ***Altaire*** MRI System Emergency Rundown Switch Unit (ERDU) | II | The Emergency Rundown Switch Unit (ERDU), which is used to shut down the ***Altaire*** device in an emergency, was found to be defective. (Z-1542-2008) |
| Hitachi | ***Vision 5500*** Diagnostic Ultrasound Scanner | III | A software error causes a miscalculation of the left ICA/CCA ratio when using the carotid calculation package for patient scans. (Z-1571-2008) |
| Hologic | Various ***Discovery***, ***QDR4500***, ***Delphi*** and ***Explorer*** Bone Densitometers | II | Software densitometer readings for left hip and lumbar spine under certain conditions may be inaccurate. (Z-2184/2188-1991) |
| Hologic | ATEC Breast Biopsy and Excision System | II | The distal tip of the needle may become detached and remain in the patient, requiring surgical removal. (Z-0275-2009) |
| Hologic | QDR X-ray Bone Densitometers Software | II | Software error may lead to a high estimate of major fracture probability. (Z-0449-2009) |
| Hospira | ***LifeCare*** PCA Label Utility | II | Incorrect dosage labels were created. (Z-1181-2008) |
| Hudson RCI Tecate | Weck ***DuraHook*** | II | The bands are breaking within the sealed packaging or in use prior to the expiration dates. (Z-1856/1857-2008) |
| ICU Medical | Hospira ***Intralock*** Lipid Compatible 3-Way Stopcock; Hospira Monitoring Kit; Hospira Left Heart Kit; ICU Medical Cath Lab Kit | II | Improper orientation of the stopcock handle questions whether there is an adequate gas path to assure sterility, which presents a possible compromise of sterility. (Z-2205/2208-2008) |
| I-Flow | ***On-Q PainBuster*** Infusion Pump | II | Box may contain the wrong product. (Z-1869-2008) |
| I-Flow | ***On-Q C-bloc*** | II | Devices may contain an incorrect fill port label. (Z-2133-2008) |
| Imaging Sciences International | ***i-CAT*** Dental Imaging Systems | II | There is incorrect scatter information in the manual. (Z-1645/1646-2008) |
| Immunodiagnostics Systems | IDS 25-Hydroxy Vitamin D EIA Enzymeimmunoassay | III | A small number of customers have experienced low absorbance values when using kits from this batch. (Z-0173-2009) |
| Impac Medical Systems | ***Mosaiq*** Sequencer | II | Software issue may result in change to intended treatment field, potentially resulting in mistreatment. (Z-1515-2008) |
| Infectio Diagnostic | ***GeneOhm*** MRSA | II | The product has the potential to identify a patient as falsely positive for colonization with methicillin-resistant *Staphylococcus aureus*. (Z-0225/0226-2009) |

| Manufacturer | Product | Class | Reason |
|---|---|---|---|
| Instituit Strauman | ***Straumann*** Narrow Connection Closure Screw | III | Contains closure screws for the regular connection (RC) bone-level implant. The RC closures screw is larger and will not fit into the narrow connection implant. (Z-1037-2008) |
| Instituit Strauman | Handpiece Driver for RN Solid Abutment | III | Handpiece driver is out-of-specification and will not function with the dental solid abutment. (Z-1876-2008) |
| Integra LifeSciences | Dermal Regeneration Template | III | Product was labeled with an expiration date of May 2010, while the actual expiration date should be April 2010. (Z-2328-2008) |
| Integra LifeSciences | ***NeuroSensor*** Probe | II | Due to a manufacturing error, the ICP reading could be inaccurate to the extent that they exceed label claims. (Z-1191-2008) |
| Integra LifeSciences | Gravity-Compensating Accessory | I | Product has the potential for leakage under certain conditions. (Z-0458-2009) |
| Integra LifeSciences | Disposable Convenience Kit | II | ***Hep-Lock*** flush vials included in PICC insertion trays contain contaminated heparin. (Z-1635-2008) |
| International Technidyne | ***AVOXimeter 1000*** and ***1000E*** Oximeters; ***4000*** Co-Oximeter | II | Instruments built or repaired were inadvertently left with the "Diagnostic Mode" enabled when shipped to customers. (Z-1237/1239-2008) |
| Interpore Cross International | ***InterGro PLUS***; ***Allogenix*** | III | A human tissue supplier used unapproved diagnostic testing on certain lots of distributed donor tissue instead of the FDA-approved screening test. (Z-0618/0619-2008) |
| Interventional Technologies | ***Flextome*** Cutting Balloon Device Over-the-Wire Delivery System | II | An incorrect compliance chart was packaged inside the sterile pouch of device. (Z-0621-2009) |
| Intraop Medical | ***Mobetron*** Mobile Electron Linear Accelerator | II | There is a locking screw/nut failure, which may result in a treatment head dropping, potentially impacting the patient. (Z-0014-2009) |
| Intuitive Surgical | ***EndoWrist*** | II | Devices were incorrectly labeled with a "CF" symbol, not the proper "BF" symbol, on the instrument housing. (Z-0258-2008) |
| Intuitive Surgical | Various ***da Vinci S*** Surgical System Instrument Cannulas | II | Devices may have a ridge on the side of the cannula, which has the potential to abrade instrument shafts and generate black particulate matter. (Z-0657/0659-2008) |
| Intuitive Surgical | ***da Vinci S*** Instrument Cannula | II | The cannula may have a sharp edge on the inner diameter of the cannula. The defective cannula may cause particulate shavings to be skive (scraping) from the instrument shafts during surgery. (Z-0669-2008) |
| Intuitive Surgical | ***da Vinci S*** Surgical System | II | Software anomalies could cause product failure during use, or on start-up. (Z-0079-2008) |
| Intuitive Surgical | Endoscopic Instrument Control System | II | The firm installed incorrect fuses. (Z-0151/0152-2008) |
| Intuitive Surgical | ***da Vinci S*** Surgical System | II | Device may not respond immediately to a user's command, such as "Master Clutch" or "Camera Control." (Z-1180-2008) |
| Intuitive Surgical | ***da Vinci*** Surgical System | II | The product has a software interface problem. (Z-1811-2008) |

| Manufacturer | Product | Class | Reason |
|---|---|---|---|
| Intuitive Surgical | ***da Vinci S*** Surgical System | II | Defective software chip may cause the system to fail and lock up. (Z-2204-2008) |
| Iverness Medical BioStar | ***BioStar*** OIA FLU AB | II | Diagnostic kits for flu were distributed with incorrect components. (Z-0212-2009) |
| JT Posey | Synthetic Leather and Biothane Waist and Wrist Restraints | II | Failure to restrain. (Z-0286-2009) |
| Jabil Circuit | ***EvoTech*** Endoscope Cleaner & Reprocessor | II | Cleaning cycles are being cancelled. (Z-1368/1369-2008) |
| JP Products | ***Maximo*** Concepts Alcohol Breath Tester | II | Marketed without FDA 510(k) clearance. (Z-0697-2008) |
| Keeler | ***All Pupil II*** Indirect Ophthalmoscope | II | Good manufacturing practice deficiencies may compromise the safety and effectiveness of the device. (Z-1132-2008) |
| Kentec Medical | Reusable Ohmeda-Compatible Finger-Clip Sensor | II | Sensors are missing an additional diode and higher resistor in its existing configuration. (Z-1188-2008) |
| Kerr | Premise Kits | II | Material appears to stiffen and become difficult to extrude over time. (Z-0230/0270-2009) |
| Kodak Electronic Products | ***DirectView*** Model DR 3000 System | II | The U-arm positioner starts to move without command from the operator and/or can unexpectedly start movement if the system is powered down and re-energized after a collision has occurred with the quantum table. (Z-0731-2008) |
| Kyphon | Functional Anesthetic Discography Catheter System and Introducer Needle | II | Guide wire broke during the functional anesthetic discography procedure. (Z-0948/0949-2008) |
| Kyphon | ***X-STOP*** Interspinous Process Decompression System | II | Physician instructions revised due to product breakage. (Z-1765-2008) |
| Kyphon | ***KyphX*** Osteo Introducer System With Blunt Tip Introducer Stylet | II | Some products may contain the incorrect introducer stylet. (Z-2347-2008) |
| Levitronix | ***CentriMag*** Primary System and Backup Console | I | Interruption of ***CentriMag*** support may occur when using a ValleyLab ***Force FX-C*** electrocautery unit. (Z-1901/1902-2008) |
| LifeCell | ***AlloCraft DBM*** with Syringe Assembly | III | Diagnostic test kits were used in lieu of a donor screening test kits for HBsAG and HBcAB. (Z-1298/1299-2008) |
| LifeLink | ***OsteoStim*** Cervical Allograft | III | Tissue supplier used unapproved diagnostic testing on donor tissue instead of the FDA-approved donor-screening test. (Z-0825-2008) |
| LifeScan | ***OneTouch*** Data Management Software | III | A software compatibility issue may cause the blood glucose meter to cease operations and freeze temporarily. (Z-1317-2008) |
| LifeScan | ***OneTouch Ultra*** Test Strips | II | Products exceed the inaccuracy threshold. (Z-0004-2009) |

| Manufacturer | Product | Class | Reason |
|---|---|---|---|
| Liko AB | ***Universal SlingBar 350***, ***450*** and ***600*** | II | A component securing the ***SlingBar*** to the patient lift may experience a nut unthreading, resulting in the sling bar detaching from the lift. (Z-2315/2320-2008) |
| Linemaster Switch | Wireless Footswitch Accessory | II | Surgical equipment, activated by a wireless foot switch, may remain powered-on when switch is no longer depressed. (Z-0933-2008) |
| Linvatec | CABG Pack Surgical Convenience Kit | II | Component of convenience kit may not be sterile. (Z-2197-2008) |
| Linvatec | Ultrapower Burs | II | Devices may have compromised sterility due to an improper seal. (Z-0711-2008) |
| Lorad | ***Selenia*** Full-Field Digital Mammography System | III | The new software version contained a magnification factor that shows CAD markers misaligned with the identified indications. (Z-1546-2008) |
| Lumenis | ***SlimLine 200*** Micron Holmium Fiber Delivery Device | II | The outer pouch is labeled "200-micron fiber"; however, the inner pouch's label affixed to the product indicates that it is 365-micron fiber. (Z-0585-2008) |
| Mainline Technology | Confirms Strep A | II | Use of an incorrect dropper tip on the dispenser may result in false-positive Group A *streptococcal* results. (Z-2427-2008) |
| Mallinckrodt | ***OptiVantage DH*** Injection System | II | Screws can begin to loosen and shear off to the point of the J-bow, falling from the suspension system. (Z-1694-2008) |
| Maquet | Accessory Head Rest | II | During installation or cleaning, there is a risk of crushing the finger by handling the headrest in the area of the gas strut while simultaneously actuating the release lever. (Z-0161-2009) |
| Maquet | ***SERVO-i*** and ***SERVO-s*** Ventilator Systems | II | There is potentially defective crimpings at the point connector attached to the cable. (Z-2442/2443-2008) |
| Maxon Motor Interlectric | ***Zyoptix XP*** Microkeratome | II | The plastic tip on the drive shaft may come off the shaft and cause the blade to stop oscillating. (Z-0103/0104-2009) |
| McMahon Medical | Covidien/Mallinckrodt ***CT9000***/***CT9000*** ADV | II | The tubing metal begins to crack and thin. (Z-1828-2008) |
| Med-Tec | MT-APSD-2.4 Type-5 Thermoplastic Mask | III | The mask is mislabeled with the incorrect part number. (Z-1608-2008) |
| Medacta International | ***AMIS*** Universal Table for Leg Positioner | II | Improper connection of the table clamping mechanism may result in the AMIS table becoming separated from the surgical table, resulting in injury to the patient. (Z-1870-2008) |
| Medcon | ***Horizon*** Cardiology Hemo Monitoring System | II | Some power grade supplies may not provide reliable power output. (Z-0710-2008) |
| Medefil | Heparin I.V. Flush Syringe | II | The heparin lock flush solution was manufactured from contaminated heparin sodium. (Z-1543/1545-2008) |
| Medela | Suction Jar Lid for ***Vario 18*** Vacuum Pump | II | Pumps were provided with an incorrect suction jar lid that did not have the correct conical connection for the vacuum tube. (Z-2168-2008) |
| Medical Components | CMS-MST572 and ***Pro-PICC CT*** Insertion Kits | II | Kits contain an incorrect component. (Z-1909/1910-2008) |
| Medical Device Technologies | ***Hawkins III*** Breast Localization Needle | II | The sterility of the product cannot be guaranteed. (Z-1878-2008) |

| Manufacturer | Product | Class | Reason |
|---|---|---|---|
| Medison | Biopsy Guide Starter Kits | II | Kits do not contain adequate labeling instructions. (Z-2013/2015-2008) |
| Medline Industries | Latex-Free C-Section CDS-LF; Latex-Free Vaginal Delivery CDS-LF; Latex-Free Labor Kit & Postpartum CDS-LF; Latex-Free Labor & Delivery CDS-LF; Latex-Free Mom/Baby Admit Kit | II | The latex-free packs contain a latex ***Nuk*** pacifier. (Z-0015/0019-2009) |
| Medtox Diagnostics | ***MEDTOXscan*** Reader | II | Reader was marketed without FDA 510(k) clearance. (Z-2202-2008) |
| Medtronic | ***Cardioblate Gemini-s*** Surgical Ablation Device | II | The polycarbonate distal coil retainer can fail during the course of a procedure, potentially resulting in an inability to apply the necessary jaw-closure force. (Z-0727-2008) |
| Medtronic | ***AneuRx AAAdvantage*** Endovascular Stent Graft with ***Xcelerant*** Delivery System | II | Device sterility may be compromised as evidenced by a loss of outer package integrity. (Z-0689-2008) |
| Medtronic | ***AneuRx AAAdvantage*** Endovascular Stent Graft with ***Xcelerant*** Delivery System | II | Products may contain elevated endotoxin (pyrogen) levels above the firm's specifications, and the product is labeled as containing no pyrogen. (Z-1918-2008) |
| Medtronic | ***Hall Easy-Fit*** Prosthetic Heart Valve | II | The holder of the valve was incorrectly secured to the valve. This could potentially make it difficult to easily disengage the holder from the valve. (Z-1774/1775-2008) |
| Medtronic | ***Nexframe*** Stereotactic System Kits | II | Some failures were for damage to the outer pouch, while another set of failures were for the seals on the pouch. (Z-0849-2008) |
| Medtronic | ***Trillium Affinity NT***; Blood Collection Reservoir | III | Oxygenators and reservoirs contain components made from an unapproved resin. (Z-0476/0477-2008) |
| Medtronic | ***Affinity NT*** Hollow Fiber Oxygenator with Carmeda BioActive Surface; Extracorporeal Circuit with Bio-Active Surface; Affinity Pediatric Arterial Filter; Affinity NT Hollow Fiber Oxygenator with Carmeda BioActive Surface; Venous Cannulae with Carmeda BioActive Surface; Various Aterial Cannulae; ***Bio-Medicus*** Femoral Cannula/Introducer; Bio-Medicus Percutaneous Cannula & Introducer Set; Catheter, Cannula and Tubing | II | Products were manufactured with heparin that was contaminated with oversulfated chondroitin sulfate. (Z-1919/1930-2008) |

| Manufacturer | Product | Class | Reason |
|---|---|---|---|
| Medtronic | ***Trillium Affinity NT*** Hollow-Fiber Oxygenator with Trillium Biopassive Surface | II | Products were manufactured with heparin batches contaminated with oversulfated chondroitin sulfate. (Z-2005-2008) |
| Medtronic | ***VNUS*** Medical U-CLIP Removal Tool | II | The nose-cone attachment on the body of the removal tool may not contain sufficient adhesive, which can allow the nose cone to separate from the body of the device. (Z-1609-2008) |
| Medtronic | BI-700-00027 ***O-ARM 1000*** Imaging System | II | Failure to comply with EER/AKR limits due to misinterpretation of the measurement requirements specified in 21 CFR 1020.32(d)(3)(iii). (Z-2034-2008) |
| Medtronic | ***SynchroMed EL*** Infusion Pump | I | Pump motor stalls due to gear-shaft wear. (Z-0739/0824-2008) |
| Medtronic | ***Pro Clinical*** Information Center | II | Pumps can stall due to gear-shaft wear. (Z-0280-2008) |
| Medtronic | ***SynchroMed EL*** Programmable Pumps | II | Pumps can stall due to gear -haft wear. (Z-0950/0957-2008) |
| Medtronic | ***SynchroMed EL***, ***SynchroMed II*** and ***IsoMed*** Infusion Pumps | I | Pumps used with the use of opioids, ***Baclofen***, pharmacy-compounded Baclofen and other drugs, as well as with other pharmacological admixtures, will cause the patient to develop an inflammatory mass. (Z-1142/1154-2008) |
| Medtronic | Intrathecal Catheter Pump Segment Revision Kit | II | Kits were packaged with the incorrect connector pin. (Z-1308-2008) |
| Medtronic | ***SynchroMed II*** Sutureless Pump Connector Revision Kit; Intrathecal Catheters | II | The catheters cannot completely engage with the Model 700-04M portal connector. (Z-2171/2174-2008) |
| Medtronic | ***Indura IP*** Intrathecal Catheter; Sutureless Pump Connector Revision Kit; and Intrathecal Catheter Pump Segment Revision Kit | I | Disconnection of the catheters from the catheter port on the pump, or occlusion between the sutureless pump connector and the catheter port on the pump. (Z-2380/2383-2008) |
| Medtronic | ***Midas Rex Legend*** Tapered Dissecting Tool | II | Cutting flute geometry of surgical dissecting tools may be outside of established tolerance. (Z-2156-2008) |
| Medtronic | Low Impedance Lead Kit for Spinal Cord Stimulation | II | Product contains accessory stylets that are not the correct length. (Z-1912-2008) |
| Medtronic | Lead Kit for Spinal Cord Stimulation | II | The package labeling incorrectly states the lead length is 28 cm when it should state "20 cm." (Z-2241-2008) |
| Medtronic | ***Kinetra*** and ***Soletra*** Neurostimulators | II | Separation of internal connections between the electronic circuit and battery may lead to sudden cessation of therapy. (Z-0693/0964-2008) |

| Manufacturer | Product | Class | Reason |
|---|---|---|---|
| Medtronic | Lead Kit for Deep Brain Stimulation | II | Leads are damaged at the proximal connector end of the lead when the lead cap is used in the implant procedure. (Z-0184/0187-2009) |
| Medtronic | ***Synchromed II*** Programmable Pump | II | Pumps may have been manufactured without propellant. (Z-2181/2182-2008) |
| Medtronic | ***Satellite*** Spinal System Primary User Group Reference Guide; Satellite Spinal System Surgical Technique | II | Marketed without FDA 510(k) clearance. (Z-0192/0210-2008) |
| Mepy Systems | Single-Use Sterile Puncture Attachment Used with BK Medical Ultrasound Equipment | II | Marketed without FDA 510(k) clearance. (Z-0504-2009) |
| Merit Medical Systems | Fluid Administration Set | II | Convenience kits may contain non-filtered drip chambers. (Z-1800/1807-2008) |
| Merit Medical Systems | Custom Angiographic Kit | II | Convenience kits may be non-sterile due to inadequate package sealing. (Z-1699/1701-2008) |
| Merit Medical Systems | ***Fountain*** Infusion System | II | Catheters were packaged with occluding wires that were too long for the catheter. (Z-2107-2008) |
| Merit Medical Systems | Control Syringes | II | Syringes may be non-sterile due to holes in the packaging. (Z-2366/2368-2008) |
| Merivaara | Surgical Table Column Casing Revision B | II | Potential exists for the energy chain, which is responsible for protecting hydraulic and electrical cables during up-and-down motion on the surgical table, to become lodged between column case sections, resulting in possible reduction or loss of function to hand and/or foot controls, or possible involuntary movement of the table. (Z-2189-2008) |
| Merivaara | ***Vertier*** Surgical Table | II | Hydraulic lines responsible for tilting the surgical table have the potential to be severed when articulating table to its lowest position, possibly resulting in the unexpected and rapid movement of the table. (Z-2376/2379-2008) |
| Microbiologics | *Proteus vulgaris* ***DuoPack*** | II | ***DuoPacks*** contained *Listeria monocytogenes* instead of the labeled *Proteus vulgaris*. (Z-0456-2008) |
| Microgenics | Ammonia/Ethanol/$CO_2$ Calibrator, Control N and Control A | II | Undetected high-quality control recovery in bicarbonate assay. (Z-0377/0379-2008) |
| Micropower Electronics | ***Fast-Pak*** Batteries | II | Batteries labeled as "2.4-amp/hour batteries"; however, they are 1.0-amp/hour batteries. (Z-1567-2008) |
| Midwest Plastics | ***GEM*** 2753 Microvascular Anastomotic Coupler | II | Coupler rings may slip out of the delivery tool caused by jaws larger-than-specification. (Z-2138-2008) |
| MIMvista | ***MIM 4.0*** and ***4.1*** | II | There is an error that may occur during the calculation of statistics using the "SUV Tool" or "Contour Statistics." (Z-1827-2008) |

| Manufacturer | Product | Class | Reason |
|---|---|---|---|
| Mindray | ***AS3000*** Anesthesia Delivery System | II | The threadlocker of the caster (wheels) may not have been used, which may allow the caster to loosen and possibly separate from the unit. Also, the use of select brands of pre-pack absorber in the absorber canister has been associated, in some cases, with gas leakage around the pre-pack, rather than through the absorber material. (Z-0319-2009) |
| Mini-Mitter | ***Actiwatch*** | II | The devices have a memory chip that has a limited number of read/write cycles, which can trigger set-up information, and/or subject information anomalies or intermittent communication annomalies. (Z-0324/0327-2008) |
| Minntech | Automatic Endoscope Reprocessor | II | Residual high-level disinfectant solution remains in endoscopes that have been reprocessed in the Automatic Endoscope Reprocessor. (Z-0281-2009) |
| Mycoal Products | ***Icy Hot*** Heat Therapy Air-Activated Heat Patch; ***Aspercreme*** Pain-Relieving Creme with Aloe | II | Skin irritation and burns with product usage. (Z-1197/1198-2008) |
| Myelotec | Steerable Video-Guided Catheter | II | Product may contain inappropriate information in its label insert that refers to the product's use with energy-delivering instrumentation. (Z-0586/0587-2008) |
| Nanosphere | Warfarin Metabolism Nucleic Acid Test Cartridge | II | A warfarin 2C9*2 mutant capture signal was found to be high enough to result in an aberrant result. (Z-1383-2008) |
| National Biological | ***Houva III*** Phototherapy System | III | Software allows operator to override "low-line voltage" error warning and store light-intensity value. (Z-1309-2008) |
| Navilyst Medical | ***NAMIC*** Custom Angiographic Kit | II | A specific batch of the product may contain loose plastic particulates in the fluid pathway. (Z-0287-2009) |
| Naviscan PET Systems | ***PEM Flex Solo II*** PET Scanner | II | The motorized compression exceeded 25 pounds of compression force during the pre-scan positioning of the patient. (Z-2229-2008) |
| Nelicor Puritan Bennett | 800 Series Ventilator Backup Power Source | II | Wiring in the battery backup power supply may short and cause thermal damage to the ventilator. (Z-1692-2008) |
| NeoMedix | ***Trabectome*** I/A Console | II | The pinch valve in a few pumps may not consistently open to allow irrigation flow. (Z-0071-2008) |
| Nerl Diagnostics | Glucose Tolerance Beverage | II | Beverage may contain glass particles. (Z-0278-2009) |
| NewDeal | ***QWIX*** Screw | II | Screws have been etched and labeled with an incorrect length. (Z-1445/1446-2008) |
| NewDeal | ***PANTA*** Nails | II | The internal thread for certain nails may present an insufficient depth and may not allow the engagement of the threaded part of the compression device. (Z-1877-2008) |
| NewDeal | ***Uni-CP*** Compression Forceps | II | The forceps may break during the compression of the ***Uni-CP*** plate. (Z-0307-2009) |

| Manufacturer | Product | Class | Reason |
|---|---|---|---|
| Nicolet Biomedical | ICU Monitor Modular Neurodiagnostic System | III | Monitor freezes up during operation when using the "Digital Video" option. (Z-0126-2008) |
| Nobel Biocare | ***NobelReplace*** Tapered Groovy RP | III | Device has an incorrect cap label. (Z-2240-2008) |
| Nonin Medical | ***PalmSAT*** Handheld Pulse Oximeter | II | The label on the back of the device may show "Model 2500A" rather than "Model 2500." (Z-0843-2008) |
| Nordisk Rontgen Teknik | ***Precision*** MPi | II | The collimator did not contain a label identifying the device as being certified to comply with applicable requirements of the X-ray performance standard. (Z-2142/2144-2008) |
| Northwest Medical Physics Equipment | ***Isoloc*** Software | II | A localization may be produced which has the incorrect moves. (Z-2137-2008) |
| Nova Biomedical | ***Nova 8*** Analyzer Calibrator Pack | III | Elevated "Normalized Ionized Calcium" (nCa) and "Normalized Ionized Magnesium" (nMg) calculated values on patient samples. (Z-0295-2008) |
| Nova Biomedical | ***EZ CHEM*** Creatinine Meter, Control Solution and Linearity Solution | II | Creatinine results were lower than the laboratory reference method. (Z-0726-2008) |
| Nova Biomedical | ***Varta Easypack XL*** Lithium Polymer Batteries | II | Lithium batteries may fail if the glucose or creatinine meters have been dropped. (Z-1472-2008) |
| Nypro | ***UniCel Dxl*** Access Immunoassay Systems Reaction Vessels | II | Vessels have been found to be defective, and there is a potential for an increase in signal leading to an erroneous result. (Z-1108-2008) |
| Nypro | Active Life Little Ones One-Piece Custom Urostomy Pouch | III | The market unit carton label reads "5/8-1 inch," and it should read "5/16-1 inch." (Z-1179-2008) |
| Nypro | ***ACIST Bracco AngioTouch*** Kit | II | Some of the sterile package seals were breached. (Z-2406-2008) |
| Oasis Medical | Various Surgical Knives | II | The device is puncturing the packing during handling. Once the packaging is damaged, the product is no longer sterile as labeled. (Z-0485/0516-2008) |
| OEC Medical Systems | ***OEC 9800*** and ***9900*** Image-Intensified Fluoroscopic X-ray System | II | Use of existing four-pedal footswitch on a different machine may cause various operational errors. (Z-1705/1706-2008) |
| OEC Medical Systems | ***OEC 9600*** C-Arm Fluoroscopy System | II | Secondary collimator filters may be missing on certain X-ray units. (Z-1709-2008) |
| OEC Medical Systems | ***OEC 9900*** Mobile Fluoroscopic X-ray System | II | Failure to apply the entrance exposure rate tube current limit calibration to the automatic exposure rate control system when the anatomical profile mode is changed from the default selection to another selection. (Z-0368-2008) |
| OEC Medical Systems | ***OEC 9800*** and ***9900*** Fluoroscopic X-ray Systems. | II | Beam limitation may be non-compliant on some X-ray units. (Z-1884/1885-2008) |

| Manufacturer | Product | Class | Reason |
|---|---|---|---|
| Ondal Indust | Circlip component of the Stryker Flat Panel and Navigation Arm System | II | Circlip component used to suspend flat panel and navigation arm system may become dislodged. (Z-0182-2009) |
| Onset Medical | ***Pathway*** Balloon Expandable Ureteral Access Sheath | II | Users experience difficulty in removing the sheath. (Z-0905/0913-2008) |
| Onset Medical | ***Pathway*** Balloon Expandable Ureteral Access Sheath | III | Users experience difficulty in removing the sheath. (Z-0912-2008) |
| OraSure Technologies | Cannabinoids Intercept Micro Plate EIA 100 Plate Kit | III | Intermittent high-absorbance readings. (Z-0481-2009) |
| OraSure Technologies | Micro Plate EIA Oral Fluid Positive Control | III | Results with false-positive test. (Z-0477/0479-2009) |
| Organogenesis | ***Apligraf*** | II | Units were reported to have contamination in the agarose nutrient medium. (Z-0675-2008) |
| Ormco | ***Grengloo*** Bracket Adhesive and Tooth Conditioner | II | Product was mislabeled with incorrect expiration date. (Z-0916-2008) |
| Orthofix | ***TrueLok*** External Ring Fixation System | II | Graduated markings on telescoping bone distractors were reversed, causing the distractors to compress rather than distract the treatment site when adjusted. (Z-0674-2008) |
| Orthosoft | Universal Optical Tracker Fixation | II | Instrument may break during use, resulting in surgical delay and an increased risk of infection. (Z-2445-2008) |
| Orthosoft | ***Quicklock*** Tracker | II | The three-point array may break during use, resulting in surgical delay and an increased risk of infection. (Z-2444-2008) |
| Oscor | Permanent Pacing Lead | II | The O-rings are over-tolerance, making it hard to connect the leads to the pacemaker. (Z-2333-2008) |
| Oscor | ***Adelante*** Luer-Lock Peel Away Introducer Set | II | Difficulty breaking the sheath hub, and subsequently to peel the sheath off. (Z-0130-2009) |
| Otsuka Electronics | ***UBiT-IR300*** Infrared Spectrophotometer | II | Device power supply may overheat and cause smoke to be emitted from the device. (Z-1749-2008) |
| Pacific Consolidated Industries | Mobile Oxygen Storage Tank | I | The firm received two complaints of ruptured bourdon tubes that had resulted in bellowed-out face gauges. (Z-2201-2008) |
| Pacific Device | Impulse Angiographic Catheters | II | Flash may be protruding from the lumen of the catheter shaft. (Z-0935/0945-2008) |
| Parks Medical Electronics | Ultrasonic Doppler Flow Detectors and Dual Frequency Doppler Vascular Flow Detector | III | The wrong acid flux was used on circuit boards, which may lead to premature battery failure. (Z-0670/0673-2008) |
| Patterson Machine | ***Dynasty*** Trial Shell | II | Trials are 2.5 mm larger than marked. (Z-2215/2218-2008) |

| Manufacturer | Product | Class | Reason |
|---|---|---|---|
| PGP | Accelerator Device Manager | II | Sample identification and/or patient identification numbers that contain more than 12 characters were truncated to the final 12 characters. (Z-0551-2008) |
| Pharmacia Diagnostics | ***Healon D*** Ophthalmic Viscosurgical Device | I | Endotoxin levels above specifications have been noted in some syringes. (Z-0343-2009) |
| Philips and Neusoft Medical Systems | ***NeuViz Dual*** Computed Tomography Scanner System | II | Potential for "R-host" box and components inside to be detached of its mounting during the gantry rotor rotation. (Z-2307-2008) |
| Philips and Neusoft Medical Systems | ***NeuViz Dual*** Computed Tomography Scanner System | II | Labeling of patient position on scanned image does not match actual patient orientation. (Z-2235-2008) |
| Philips | ***iSite*** PACS | II | Device may incorrectly display of one of the patient's images. (Z-1141-2008) |
| Philips | ***iSite*** PACS | II | When using the "Freehand Region of Interest" tool, errors may occur in area calculation yielding incorrect results. (Z-1443/1444-2008) |
| Philips | ***iSite*** PACS | II | Scout line and localizer crosshair on MPR images will display in the incorrect position under certain circumstances. (Z-2346-2008) |
| Philips | ***iSite*** PACS | II | There is a potential to display a patient on the canvas page that is different from the patient whose images are displayed on diagnostic monitors when using conference presentation states and when opening two or more studies from a folder or an exam work list. There also is the potential to miscalculate measurements when pixel spacing and imager pixel spacing DICOM tag values are both present and different. (Z-0118-2009) |
| Philips | General X-Ray System Types with Digital Spot Imaging Software | II | X-ray images may be stored in the wrong patient file or corrupted. (Z-2160-2008) |
| Philips | ***Page Writer Touch*** Cardiograph | II | When using the 16-lead "Patient Interface Module," lead tracings of "V3R" and "V4R" are reversed in the extended lead modes of "Pediatric" and "Balanced." (Z-0124-2008) |
| Philips | ***CareVue*** Chart Release C; ***IntelliVue*** Clinical Information Portfolio Critical Care Release D | II | Medications prescribed for one patient were printed on the record of another patient. (Z-1540/1541-2008) |
| Philips | ***SureSigns VS3*** Vital Signs Monitor | II | Some users assumed that the $SpO_2$ non-pulsatile and $SpO_2$ no-sensor technical alarms were enabled when the monitor was not in interval non-invasive blood pressure mode. (Z-1911-2008) |
| Philips | ***HeartStart MRx*** Defibrillator/Monitor | II | The device may have a defective internal memory card. (Z-2337-2008) |
| Philips | Telemonitoring System Software | III | If "Weight Limits" is edited, values will return to default values that were deleted. (Z-2369-2008) |
| Philips | Telemonitoring Clinical Review Software | II | A multiprint report may contain incorrect vital data for patients. (Z-0100-2009) |

| Manufacturer | Product | Class | Reason |
|---|---|---|---|
| Philips | Cardiac Viewer or Pulmonary Viewer Application | II | Incorrect measurement will occur when the operator uses the distance or area measurement function. (Z-0366/0367-2008) |
| Philips | ***Gemini*** PET/CT Systems | II | Artifacts may appear in some images from head scans on the CT subsystem. (Z-0461/0462-2008) |
| Philips | ***Axis*** and ***Irix*** Gamma Cameras; Rotate Motion Shunt Resistor Kit | III | The rotate motion shunt resistor may overheat and results in the appearance of smoke, a burning smell and an electronic stop condition, which will disable the gamma camera rotate motion and all other motions. (Z-1510/1512-2008) |
| Philips | Respiratory Gating System | II | A leak between the tube interface and the outlet tube of the transducer may result in a failure to produce respiratory correlated images. (Z-0132-2009) |
| Philips | ***EasyVision*** Radiological Image Processor | II | Inaccurate measurements when exporting radiography images to the picture archiving and communications system. (Z-2053-2008) |
| Philips | ***Essenta DR*** Digital Multifunctional X-ray System | III | Bright artifacts may appear on a patient image from a previous exposure, which might lead to a misdiagnosis. (Z-1895-2008) |
| Philips | AD 7 Patient Table supplied with ***Allura Xper FD10*** and ***FD10/10*** | II | Potential for radiologic patient table to become immobile and unable to move again due to force-sensor sensitivity to electromagnetic radiation. (Z-1642-2008) |
| Philips | ***OmniDiagnost Eleva*** X-ray System | II | Unexpected movement of the X-ray table may occur. (Z-1374-2008) |
| Philips | ***MultiDiagnost Eleva*** Flat Detector X-ray System | II | There may be a delay in imaging. (Z-1137-2008) |
| Philips | ***Gallileo*** Automatic Collimator | II | The collimator could fall from the X-ray stand due to loosening screws. (Z-1886-2008) |
| Philips | Cardiac Viewer or Pulmonary Viewer | II | A software defect causes incorrect measurements in derived images, which are zoomed and saved in a batch file. (Z-0676-2008) |
| Philips | Radiation Protective Eyewear | III | Eyewear does not meet the radiation protection levels stated on the labeling. (Z-2167-2008) |
| Physio-Control | ***LifePak 20*** Defibrillator/Monitor | II | There is a potential for delay in therapy or prevention of defibrillation therapy due to corrosion of the printed circuit board assemblies. (Z-1050-2008) |
| Physio-Control | ***LifePak CR Plus*** Automated External Defibrillator | I | Device is configured with the incorrect software. (Z-2341-2008) |
| Physio-Control | ***LifePak 12*** Defibrillator/Monitor | II | A solder defect could prevent the device from providing a defibrillation shock. (Z-1858-2008) |
| Physio-Control | ***LifePak 20*** and ***20e*** Defibrillator/Monitors with Keypad Replacements | II | A thicker keypad may prevent the door from fully latching closed. (Z-2009/2011-2008) |

| Manufacturer | Product | Class | Reason |
|---|---|---|---|
| Physio-Control | ***LifePak 1000*** defibrillator | II | Potential for the display screen to dim and eventually go blank. (Z-1656-2008) |
| Physio-Control | Internal Defibrillator Handles; Internal Defibrillation Electrodes | II | Sterilization methods described in labeling may be ineffective and may cause damage or corrosion to the paddles or handles. (Z-2035/2036-2008) |
| Physio-Control | ***LifePak CR Plus*** and ***Express*** Automated External Defibrillator | II | The device may not power on. Although it indicates it is ready for use, it would not be able to provide defibrillation therapy. (Z-0149/0150-2009) |
| Physio-Control | ***LifePak 12***, ***20*** and ***20e*** Defibrillator/Monitors | II | There is an increase in likelihood for an incorrect shock advisory algorithm decision if the "Auto Analyze" setting in is on. (Z-1904/1906-2008) |
| Physio-Control | ***LifePak 20*** Defibrillator/Monitor | II | Potential for the coin battery to drain prematurely, causing the monitor clock time and date to be incorrect and the service light indicator to illuminate. (Z-2388-2008) |
| PML | ***LyfoCults*** *Haemophilus parainfluenzae*; ***Vitek*** NH ID Card (NHI) Set; IDS Rapid NH QC Set | III | Test was manufactured with *Cryptococcus neoformans* instead of *Haemophilus parainfluenzae*. (Z-0721/0723-2008) |
| Pointe Scientific | Liquid Alkaline Phosphatase Reagent Sets | II | Product may be contaminated with microorganisms. (Z-1353/1360-2008) |
| Pointe Scientific | Liquid ALT Reagent Set | II | Failure of the reagent to produce test results. The R1 reagent may be contaminated with microorganisms. (Z-1110/1117-2008) |
| Pointe Scientific | Liquid AST (SGOT) Reagent Set and AST R1 Reagent | II | The R1 component may be contaminated with *Serratia liquefaciens*, resulting decreased absorbance and failure of the reagent to produce test results. (Z-0171/0172-2009) |
| Pointe Scientific | Liquid Glucose HEX (R1) and (R2) Reagent Sets | II | The product isn't able to maintain stated performance specifications through the stated shelf life. (Z-0219/0224-2009) |
| Popper & Sons | ***Perfektum*** Toomey Evacuating Syringes | III | The product name on the label was erroneously declared as "***Perfektum*** Toomey Evacuating Syringes" instead of "Popper Interchangeable Hypodermic Syringes." (Z-0881-2008) |
| Porter Instrument | Bag Tee Assembly | II | Inverted check value on the bag tee assembly can cause leaking of mixed $N_2O/O_2$ gas. (Z-0228-2009) |
| Portland Orthopaedics | ***Margron DTC*** Hip Replacement System | II | The product is associated with a higher-than-average rate of hip replacement revision surgery. (Z-1931/2001-2008) |
| Precept Medical Products | Tape and Foam Fog Shield Surgical Masks | II | There are small slits under the folds of the masks. (Z-0153/0154-2008) |
| Pride Mobility Products | ***Q-Logic*** Controller Software | II | "Watchdog Timer" feature was disabled. (Z-1776-2008) |
| Primrose Medical | Dual Lumen Catheter | II | Particulate matter in the catheter. (Z-2226-2008) |
| Promega | ***RNAgents*** Total RNA Isolation System | II | Bottles were leaking Phenol:Chloroform:Isoamyl Alcohol. (Z-0483-2009) |

| Manufacturer | Product | Class | Reason |
|---|---|---|---|
| Promex Technologies | Bone Marrow Aspiration Kit | II | Kits were manufactured with syringes that expire on 10/2009 and labeled with an overall expiration of 10/2010. (Z-0272-2009) |
| Propper Manufacturing | Propper Short ***Gas-Chex*** EO Sterilization Indicators | II | A production specification discrepancy may cause the indicators to show an inaccurate result. (Z-2330-2008) |
| Propper Manufacturing | 3M ***Comply*** EO Chemical Indicators Strips | II | A production specification discrepancy may cause the indicators to show an inaccurate result, which could incorrectly lead customers to conclude the sterilization cycle was adequate. (Z-1568-2008) |
| Protech Leaded Eyewear | Radiation Reduction Gloves | II | Radiation reduction gloves were labeled as "Latex-free," but contain natural rubber latex. (Z-2335-2008) |
| Provalis Diagnostics | ***Cholestech*** GDX A1C Test Cartridge | II | The product would not meet performance claims through the end of its shelf life. (Z-2460-2008) |
| Qualigen | ***FastPack*** Total PSA Immunoassay | II | Product was not meeting product performance expectations. (Z-0500-2009) |
| RO Gulden | Ocular Conformer | III | Conformers were distributed with an expired expiration date. (Z-2302-2008) |
| Radiometer Medical | ***ABL700*** and ***ABL800 FLEX*** Analyzers | II | Reported calibration errors are not displayed on the analyzers' parameter bar screen or on the patient results when the calibration number is between 32768 and 65535, and 98303 and 131070. (Z-1653/1654-2008) |
| Radiometer Medical | Calibration 1 Solution | II | The barcode does not reflect the actual values of the solution. (Z-0457-2009) |
| Remel | ***RapID*** Inoculation Fluid | III | Use of the product with various ***RapID*** Identification systems panels may exhibit poor or no reactions. (Z-1624/1625-2008) |
| Remel | ***Xpect*** *Giardia/Cryptosporidium* Kit | II | Faint gray test lines for *Cryptosporidium* may be visible, which may be interpreted as false-positive. (Z-2432-2008) |
| Resonance Technology | ***Serene Sound*** Digital MRI Compatible High Fidelity Stereo Sound System Headset | II | Use of this product with MRI may result in the headset's cord overheating and patients experiencing burns to the skin. (Z-1823/1824-2008) |
| Respironics | ***Esprit*** Ventilator; Esprit Power Supply Snubber Board Assembly Field Replacement Unit; Esprit Power Supply | II | There have been power supply failures. (Z-2002/2004-2008) |
| Respironics | Various Devices | II | Glass fragments may present in the plastic bag material used to ship components. (Z-1055/1093-2008) |
| Respironics | ***PLV-100*** Portable Lifecare Ventilator and Power Board Kit | II | Ventilators may not trigger a signal to activate third-party remote alarms or nurse call systems upon device failure. (Z-2344/2345-2008) |
| Rita Medical Systems | ***Vortex VX*** | II | The product may contain an incorrect-sized catheter. (Z-0149-2008) |

| Manufacturer | Product | Class | Reason |
|---|---|---|---|
| Roche | LIPC Lipase Colorimetric Reagent | II | The reagent of the LDL-cholesterol assay shows a carryover effect on the lipase assay. (Z-0688-2008) |
| Roche | LDL-C, LDL-Cholesterol Plus 2nd Generation; IRON2, Iron Gen. 2; CREP2, Creatinine Plus Ver. 2; STFR Tina-quant Soluble Transferrin Receptor; HDLC3, HDL-Cholesterol Plus 3rd Generation; ALBT2, Tina-quant Albumin Gen. 2; NAPA2, N-Acetyl-Procainamide, COBAS Integra | II | Some of the labels are glossy, resulting in the bar code being difficult to read by the barcode reader. (Z-0007/0012-2009) |
| Rockwell Medical Technologies | ***RenalPure*** Liquid Acid Concentrate R-006, R-235 and R-259 Glacial Acidic Acid | II | Foil-seal deterioration is occurring on the tamper-resistant foil seals on dialysis liquid concentrate and ***Dri-Sate*** product containers older than two years. (Z-0871/0875-2008) |
| Sanmina-SCI | ***LifeBed*** Patient Vigilance System | II | Failure to recognize "Bed Exit" when the feature is active due to a software anomaly. (Z-0592-2008) |
| Sanpou Chemical | ***Ace*** Heat Therapy | II | Potential for skin irritation and burns associated with the use of this product. (Z-2431-2008) |
| Sarstedt | Safety Lancet | II | The product may not retract the lancet into the safe position inside the lancet body after the trigger is actuated. (Z-0114-2009) |
| SCC Soft Computer | ***SoftPath*** GUI Release Software | II | Loss of text misrepresented individual tissue diagnosis on the final diagnosis print out from the HIS system software. (Z-2329-2008) |
| SCC Soft Computer | ***SoftPath*** ASCII Software | II | In the creation of revised report and supplemental reports diagnosis, text was inserted from another case. (Z-2463-2008) |
| Sedecal | ***Definium 5000*** Digital Radiographic Imaging System | II | Collimator failed compliance testing due to a blade-sizing issue. (Z-1133/1134-2008) |
| Seisa | ***Frazier*** and ***Poole*** Suction Instruments | II | The pouch seal may be incomplete or not present. (Z-0555/0564-2008) |
| Seradyn | QMS Vancomycin Reagents | II | False-negative test results due to interfering substances in the patient's blood may produce erroneously low results. (Z-1102-2008) |
| Siemens | Various ***Angiostar***, ***Multistar***, ***Bicor***, ***Coroskop*** and ***Neurostar*** X-Ray Systems | II | Unintended movement of the system table and/or C-Arm. (Z-0133/0148-2009) |
| Siemens | Various ***Axiom Artis*** Systems | II | System may switch to "Emergency Fluoroscopy" mode. (Z-0312/0317-2009) |

| Manufacturer | Product | Class | Reason |
|---|---|---|---|
| Siemens | ***Leonardo*** Workstation Picture Archiving and Communication System | II | The orientation labels will be incorrectly displayed on the reconstructed ***InSpace*** 3-D image if the orientation was not originally "HFS" on the acquisition system. (Z-1038-2008) |
| Siemens | Various ***Axiom Artis*** Devices | II | Image may be calibrated to the wrong-sized catheter. (Z-0120/0128-2009) |
| Siemens | ***Axiom Luminos*** dRF with ST Filter | II | Issue may occur where an intended movement of the joystick may unintentionally initiate an X-ray exposure. (Z-0326-2009) |
| Siemens | ***Dimension*** Total Prostate Specific Antigen Flex Reagent Cartridge | II | The product may exhibit falsely elevated results. (Z-1606-2008) |
| Siemens | ***Clinitest*** hCG Cassette Pregnancy Test | II | False-positive hCG results. (Z-1475-2008) |
| Siemens | ***Magnetom Espree*** with Swiveling Operating Room Table | II | Table may experience a deadlock situation. (Z-0518-2008) |
| Siemens | ***Syngo*** Imaging System | II | A buffer overflow may occur between information system and picture system if the system experiences a high load. (Z-0732-2008) |
| Siemens | Various Magnetom Harmony Devices | II | Magnet quench; unintended-magnet of a mobile MRI system quenched into the exam room. (Z-1042/1049-2008) |
| Siemens | ***Advia Centaur*** HAV IgM | II | False-reactive specimens on the assay. (Z-1119-2008) |
| Siemens | ***Advia Centaur*** TnI-Ultra Assay | II | Falsely elevated troponin values have been reported, which are inconsistent with the patient's clinical picture and test negative by other troponin assays. (Z-0580-2008) |
| Siemens | Coat-A-Count PSA IRMA Kit | II | Kit exhibits a low bias, which is evident when comparing results with other methods. (Z-2090-2008) |
| Siemens | ***Immulite*** Progesterones | II | There is a long-standing high bias with LKPG 1,5. (Z-0524-2009) |
| Siemens | ***Syngo*** US Workplace Picture Archiving and Communication System | II | A software bug may cause inaccurate wall motion abnormality scoring results to be displayed. (Z-1138-2008) |
| Siemens | ***Syngo*** Imaging XS | II | The selected patient images on the device may display an additional image from another patient or study. (Z-1643-2008) |
| Siemens | ***Axiom Luminos*** TF | II | Liquids may enter the system and cause potential malfunction and possible hazard to patients, users or other persons. (Z-0101-2009) |
| Siemens | ***Syngo*** Imaging | II | Image may not be visible after merge. (Z-0102-2009) |
| Siemens | ***Axiom Aristos*** FX Multipurpose Radiography System | II | Tube support arm or the detecting mounting hardware may become loose at the joint with the telescope. (Z-0163-2009) |
| Siemens | ***Axiom Artis*** and ***Artis Zee*** | II | Patients could possibly fall off the table if not properly secured when moving them onto the patient table, moving them on the patient table or removing them from the patient table. (Z-0193/0194-2009) |

| Manufacturer | Product | Class | Reason |
|---|---|---|---|
| Siemens | ***Syngo MultiModality WorkPlace*** | II | Values derived from ***Dynamic*** CT data sets may be incorrect. (Z-0324-2009.) |
| Siemens | ***Biograph*** PET/CT Scanners | II | An asymmetry can be introduced into the attenuation-corrected PET images when using iterative reconstruction in combination with a specific number of subsets and reconstruction matrix sizes. (Z-0246/0252-2008) |
| Siemens | ***Acuson*** and ***Sonoline*** Antares Ultrasound Systems | II | A software problem results in on-screen indications that lead the user to believe that the patient's right and left, and the transducer orientation are oriented the same. (Z-0297/0298-2008) |
| Siemens | Various ***Simview*** Cassette Holder Electronic Imaging Devices | II | Cassette holder may become loose and result in the device dislodging and colliding with the patient. (Z-0281/0285-2008) |
| Siemens | Various ***Mevatron*** Medical Charged-Particle Radiation Therapy Systems | II | Products manufactured prior to 1999 may experience jaw field size errors during interlock, resulting in potential mistreatment if a light-field check is not performed. (Z-0677/0687-2008) |
| Siemens | ***Acuson Aspen*** Diagnostic Ultrasound System | III | A measurement error may occur. (Z-0719-2008) |
| Siemens | ***Primus*** and ***Mevatron*** Linear Accelerator Systems | II | Loose or falling-off stationary structure doors. (Z-0850/0852-2008) |
| Siemens | Various ***Mevatron***, ***Primus***, ***Oncor*** and ***Primart*** Medical Linear Accelerators | II | Linear accelerator gantry may rotate in an unexpected direction and may cause patient injury on impact. (Z-1394/1407-2008) |
| Siemens | ***Acuson Sequoia*** Diagnostic Ultrasound System | II | Measurement errors may occur. (Z-0661-2008) |
| Siemens | Various ***Coherence***, ***Primeview***, ***Impression*** and ***Syngo*** Therapy Systems | II | If the reference image has been calibrated for centering and the reference image is used for patient positioning, the image will shift when the positioning tools are used. (Z-0971/0981-2008) |
| Siemens | Linear Medical Accelerators | II | Images may potentially shift, causing an incorrect alignment of the patient, which may result in a dose to the wrong location. (Z-1768-2008) |
| Siemens | Various ***Simiview*** Systems | II | The firm sent an update instruction, "TH003/08/S," for the motion enable switch/holder assembly. (Z-2196-2008) |
| Siemens | ***Acuson*** and ***Sonoline*** Antares Ultrasound Systems | III | Software issues may result in distorted images and inaccurate measurements, which could lead to a misdiagnosis. (Z-1766/1767-2008) |

| Manufacturer | Product | Class | Reason |
|---|---|---|---|
| Siemens | Ultrasound Transducer | II | The product assembly can cause a failure of the transducer, which results in a double and/or overlapped image, which may ultimately result in misleading or false information, inability to accurately diagnose, incorrect positioning/locating/insertion of the biopsy needle and/or an interruption during the biopsy procedure. (Z-2230-2008) |
| Siemens | Radiation Therapy System | II | Under certain circumstances, the portal image may be overwritten, which may lead to incorrect dosage. (Z-2095/2104-2008) |
| Siemens | Various ***Mevatron***, ***Primus*** and ***Oncor*** Digital Linear Accelerators | II | When used with field sizes of 5 cm x 5 cm or smaller, product may leak radiation at a distance of 2 cm from the side of the applicator body up to 13%, in excess of IEC standards. (Z-1753/1763-2008) |
| Siemens | ***Acuson*** CV70 Ultrasound Systems | II | System may either display incorrect mechanical and thermal index values, or fail to display them altogether. (Z-2212-2008) |
| Siemens | ***Sonoline*** G50/G60 Ultrasound System | II | As a result of bugs and calculation errors, the firm may display incorrect or fail to display mechanical-index and thermal-index values. (Z-2468-2008) |
| Siemens | ***Acuson/Sonovista X300*** Ultrasound Systems | II | Incorrect value calculations by the device may result in inaccurate aortic stenosis estimates. (Z-0086-2009) |
| Siemens | Various ***Coherence***, ***Primeview***, ***Impression*** and ***Syngo*** Systems | II | Flat-panel positioning calibration could be off by as much as 4 mm without the machine discovering detail. (Z-0089/0099-2009) |
| Siemens | ***Artiste*** MV System | II | There is an unexpected rotation of gantry, unexpected movement of the table between beams during patient setup and single-exposure images will be overwritten by double-exposure images. (Z-0116-2009) |
| Siemens | ***Symbia*** T6 System | II | The protective plastic cap over the CT gantry power switch on the line connection box may come loose, exposing the energized electrical contacts within the switch, thereby causing an electric hazard. (Z-0189/0190-2009) |
| Siemens | Medical Charged-Particle Radiation Therapy System | II | Images viewed in the device may shift, which could result in mistreatment. (Z-1769-2008) |
| Siemens | ***Acuson X300*** Ultrasound Systems | II | Thermal Index Cranial is not displayed for the Neo-Head exam type with the C8-5 transducer. (Z-0111-2009) |
| Siemens | ***Syngo Dynamics*** 6.0 Workplace | II | A software bug may result in a transfer of patient demographic data to a different patient's file. (Z-1751-2008) |
| Siemens | ***Somatom Emotion 6*** and ***16*** | II | The power switch could break, causing the protective plastic cap to come off and exposing the energized electrical contacts within the switch. (Z-2452/2453-2008) |
| Smith & Nephew | ***Calaxo*** Bioabsorbable Interference Screw | II | Post-operative condition sterile fluid pocket has been identified, including the potential for graft failure and premature material degradation. (Z-0593/0616-2008) |
| Smith & Nephew | Flat Drain Chariker-Jeter Dressing Kits | III | Kit labels may incorrectly state that a flat drain is contained as a kit component, while some kits may contain a round drain. (Z-1620-2008) |

| Manufacturer | Product | Class | Reason |
|---|---|---|---|
| Smith & Nephew | ***Trigen*** Hind Foot Fusion Nail | II | One of the distal-locking screw holes on a hindfoot fusion nail was drilled with an incorrect trajectory. (Z-2082/2088-2008) |
| Smith & Nephew | Caption Disposable Platelet Concentrator Kit | II | Product contained a syringe whose package seal integrity can be adversely affected when the product is exposed to low atmospheric pressure. (Z-2446/2447-2008) |
| Smith & Nephew | Various ***Dyonics*** Bags | II | Integrity of the remote control bag may not be sufficient to prevent tearing or opening of the bag during use. (Z-2448/2451-2008) |
| Smiths Medical | CADD Medication Cassette Reservoirs with Clamp and Female Luer | II | Leakage may occur. (Z-0876/0879-2008) |
| Smiths Medical | ***Wallace*** Oocyte Recovery Needles | II | Needle tip may be damaged. (Z-0593-2009) |
| Smiths Medical | ***Add-On*** Kids Kit | III | The product codes are labeled incorrectly. (Z-0695/0696-2008) |
| Smiths Medical | ***FLO$_2$*** Emergency Non-rebreather High-Flow $O_2$ System***; Oxy-PEEP*** High-Flow $O_2$ | II | Device may not provide expected oxygen concentration or the expected flow rate due to an incorrectly molded part. (Z-1379/1380-2008) |
| Smiths Medical | ***Medex*** Administration Sets | III | A misbranded/mis-packaged device was distributed. (Z-1549-2008) |
| Smiths Medical | ***Deltec 3000*** and ***3100*** Large Volume Infusion Pumps | II | The product may deliver an unintended bolus if the pump door is opened and then immediately closed. (Z-1604/1605-2008) |
| Smiths Medical | ***CADD-Sentry Pro*** Medication Safety Software | II | A software anomaly may occur. (Z-0134-2008) |
| Smiths Medical | ***CADD-MS 3*** Ambulatory Infusion Pump | II | A motor problem may cause an over-delivery of insulin, which could result in injury to the user. (Z-1621-2008) |
| Smiths Medical | ***Deltec Cozmo*** Insulin Pump | II | A motor problem may cause an over-delivery of insulin, which could result in injury to the user. (Z-1622-2008) |
| Smiths Medical | ***CADD-MS 3*** Ambulatory Infusion Pump | II | The device powers down without an alarm. (Z-1641-2008) |
| Smiths Medical | ***Deltec Cozmo*** Insulin Pump | II | The pump powers down without an alarm. (Z-1590/1591-2008) |
| Smiths Medical | BCI 3180 Oximeter | II | The device's tantalum capacitors C38, C72, C74 and C98 were installed backwards during assembly. (Z-1619-2008) |
| Smiths Medical | BCI Non-Invasive Blood Pressure Monitor Product | II | Due to a component that may be installed backwards, the device may turn off or may immediately reset. (Z-1649-2008) |
| Sorin Group | Dideco ***Lilliput 1*** | II | Under certain conditions, venous reservoir on oxygenator may allow air into the system. (Z-2469-2008) |
| Spacelabs Healthcare | ***Ultraview*** Multigas Analyzer | II | Inaccurate partial pressure readings may occur. (Z-0660-2008) |

| Manufacturer | Product | Class | Reason |
|---|---|---|---|
| Spacelabs Healthcare | ***Ultraview*** Digital Telemetry Transmitter | II | Telemetry modules are failing to alarm for low heart rate and asystole. (Z-1652-2008) |
| Spacelabs Healthcare | Temperature Probe Adaptor | II | Intermittent contact of temperature probe adaptors can cause a loss of temperature monitoring, which can cause a delay in care when an alarm is missed. (Z-2314-2008) |
| Spacelabs Healthcare | ***Ultraview SL*** Command Module | II | Potential for module to fail to obtain a NIBP reading on hypertension patients. (Z-2342/2343-2008.) |
| Spacelabs Healthcare | ***Ultraview*** Digital Telemetry Transmitter | II | During battery insertion there is potential for patient waveforms to move to an open receiver module or to an occupied receiver, causing the intermittent inappropriate monitoring of both patients for several minutes. (Z-2336-2008) |
| Specialized Medical Devices | ***Acu-Loc*** Distal Radius Plate | III | Plates are incorrectly laser marked. (Z-2153-2008) |
| Spectranetics | ***Quick-Cross*** Support Catheters | II | Catheters were placed into mislabeled inner pouches. (Z-0698-2008) |
| St. Jude Medical | ***Livewire TC*** Ablation Catheter | II | The product was mis-labeled as having an 8 mm tip instead of a 4 mm tip. (Z-2313-2008) |
| St. Jude Medical | ***Atlas*** and ***Epic*** Implantable Cardioverter Defibrillators | II | A condition that could lead to a ventricular sensing anomaly was identified. (Z-1320/1347-2008) |
| Statcorp | Various Casmed Unifusors | II | Infusion Cuffs may exhibit air leakage at the union of the tube and bag, and not maintain pressure. (Z-0461/0471-2009) |
| StelKast | ***Proven*** Knee System Tibial Half Block Augmentation and Screw | III | The screws may fracture. (Z-0479/0483-2008) |
| StelKast | ***Proven*** Cemented Semi-Constrained Total Knee | II | Five three-peg patella SC1591-29 were packaged in containers labeled for SC1591-38, and shared the same lot number. (Z-0308-2009) |
| Steris | C1160 Universal Flexible Processing Tray | II | Trays were not effectively sterilized. (Z-1190-2008) |
| Steris | ***Quick Connect*** Component | II | When the two inflow barbs on adapter 201048 # 4 are in a position to face one direction, the top barlock may interfere with the top surface of bottom barb of the adapter. (Z-2462-2008) |
| Steris | Small Renaissance ***Eagle 3000*** | II | Some units may have a door post-pin missing, which could cause incomplete or no engagement of the radial arms into the lock rails of the door. (Z-2350-2008) |
| Stille | ***Sonesta 6210*** Fluoroscopy Procedure Table | II | The table contains a battery backup, not mentioned in the user manual, which automatically will provide power to the electrical actuators/motions in case of a power loss from the main power supply. However, if a short circuit occurs, it can result in an uncontrolled movement of the table, which cannot be stopped by disconnecting the device from the main power supply, as the battery automatically will supply continuous power to the control box. (Z-0119-2009) |

| Manufacturer | Product | Class | Reason |
|---|---|---|---|
| Stryker | Biotech OP-1 Implant | III | The package insert was misprinted. (Z-2311-2008) |
| Stryker | OPHIT Optical Digital Visual Interface Extender | III | Product at times experiences intermittent signal loss due to electromagnetic interference. (Z-2467-2008) |
| Stryker | ***ACL Workstation*** Slider | II | The slider does not consistently lock into the workstation base. (Z-1107-2008) |
| Stryker | Rotating C-Mount Coupler | II | The coupler on this device was manufactured without set-screws that are used to hold and center the rear assembly and the endobody. (Z-1558-2008) |
| Stryker | Digital Capture System Ultra | II | Patient Identification numbers and names may be applied to images from another patient due to a software issue. (Z-1316-2008) |
| Stryker | Ureteral Kits | II | Kit fibers may not illuminate along entire length, which may result in inadequate visibility of the urethral structures during surgery. (Z-1866/1867-2008) |
| Stryker | ***Vision Elect*** HDTV Surgical Viewing Monitor | III | Knob parts stick together, resulting in poor functionality of the knob. (Z-0196-2009) |
| Stryker | ***Gamma3*** System Set Screwdriver | II | Screwdrivers have hexagon tips that were not hardened to specification. (Z-1626/1627-2008) |
| Stryker | GMRS Proximal Femoral Surgical Protocol | II | The GMRS Proximal Femoral Surgical Protocol states, "The GMRS Proximal Femoral components are fully compatible with all Stryker V40 femoral heads." This statement is incorrect and conflicts with the ***Alumina*** head label and packaging insert. (Z-0668-2008) |
| Stryker | ***Triathlon*** Baseplate Impactor Extractor | II | The device may not assemble/disassemble easily to the baseplate. (Z-1105-2008) |
| Stryker | ***Solar HA*** Humeral Stem with Plasma Coating | II | Loosening of the titanium plasma coating on the product was observed. (Z-1236-2008) |
| Stryker | ***Triathlon TS*** Femoral Trial Orthopedic Manual Surgical Instrument | II | Sharp edges will cause a glove to tear and cut someone. (Z-1572/1587-2008) |
| Stryker | ***Xcelerate*** Patella System Reamer Shaft Assembly | II | The assembly and the reamer adapter do not mate properly. (Z-1778-2008) |
| Stryker | ***Triathlon*** Revision Instruments | II | Stem trails may crack, potentially causing fragments of the plastic handle to fragment and break off completely. (Z-2157/2158-2008) |
| Stryker | ***Scorpio*** Total Knee Posteriorly Stabilized Femoral Component | II | Boxes were mislabeled. (Z-1814-2008) |
| Stryker | ***OmniFit HFx*** X-ray Templates and Sell Sheets | II | Devices were produced without a warning statement indicating a potential function of fit issue when using -3 mm and -5 mm heads or sleeves on certain stems. (Z-2054/2055-2008) |

| Manufacturer | Product | Class | Reason |
|---|---|---|---|
| Stryker | Osteonics ***Scorpio*** Total Knee | II | Component labeled and laser marked as "left" was in fact a right component. (Z-2079-2008) |
| Stryker | ***Hoffman II*** Compact Sterile Wrist Kit | II | The pin may jam into the soft-tissue protector. (Z-2080-2008) |
| Stryker | Cancellous Bone Screw | II | The screws were labeled as "25 mm" in length when it may be 20 mm in length. (Z-2007-2008) |
| Stryker | ***Scorpio*** Series 7000 Tibial Impactor/Extractor | II | There is a potential inability to release the device from a tibial baseplate during use. (Z-0115-2009) |
| Stryker | ***Omnifit*** EON Surgical Protocol | II | The "Table 2 Broach and Neck Trial Sizing" on page 3 is incorrect, reading 5mm less than what it should be for certain sizes. (Z-1750-2008) |
| Stryker | ***Scorpio*** Femoral Components | III | The labeling indicates a ***Scorpio*** PS femoral component; however, the device inside the package is actually a Scorpio CR femoral component. (Z-1381/1382-2008) |
| Stryker | Universal Notch Preparation Guide; ***X-Celerate*** Universal Block Pegless | II | Discovery of the potential for pin-and-punch interference that may result in damage to bone if a user aggressively attempts to seat an obstructed punch. (Z-1690/1691-2008) |
| Stryker | Rejuvenate Broach | II | Device was designed in a manner that may result in the potential for a medical calcar fracture. (Z-2349-2008) |
| Stryker | ***VertePort*** | II | The instructions for use included a use for which the device is not intended. (Z-1192/1195-2008) |
| Stryker | Femoral and Trial Heads | II | There may be a potential increased risk of stem neck fractures when a V40 +16mm offset femoral head is mated with certain ***Accolade*** TMZF femoral stems in patients classified as overweight or obese. (Z-0962/0970-2008) |
| Stryker | Round Fluted Bur | II | Lack of assurance of sterility. (Z-0988/1034-2008) |
| Stryker | Various Trident Devices | II | Some of the parts tested exceeded the firm's internal acceptance criteria for manufacturing residuals. (Z-1168/1174-2008) |
| Stryker | ***Navigation*** and ***Ortholock*** Pins | II | Instructions have been updated to include new warnings regarding percutaneous pin placement during surgery in order to mitigate the risk of femur fractures. (Z-2288/2294-2008) |
| Stryker | Locking Screw | II | Screws do not have locking threads. (Z-1297-2008) |
| Stryker | ***Medical Secure*** and ***Medical Epic*** Beds | II | The brakes may not have adequate holding power to lock the bed in place. (Z-1685/1689-2008) |
| Stryker | ***Sechrist*** Hyperbaric Chamber Gurney | II | The stretcher brake cams may crack while attempting to lock the stretcher brake. (Z-0734/0737-2008) |
| Stryker | Modular Replacement System Curved Cemented Stem | II | The radius of curvature may be out-of-specification to varying degrees, causing a discrepancy in the stem curvature between trials and implants. (Z-0917/0927-2008) |

| Manufacturer | Product | Class | Reason |
|---|---|---|---|
| Stryker | Advanced Cement Mixer Bowl and Base | II | Sterility may be compromised, as the packaging may have channels in the packaging seal. (Z-1106-2008) |
| Stryker | Various ***Peek Intraline*** Anchors; Wedge HS Suture ***Anchor II*** with Needles | II | Product package may crack and cause loss of sterility. (Z-1533/1538-2008) |
| Stryker | ***Serfas*** Energy Suction Probe | II | Device may not turn off after taking finger/foot off of activating switch, and may activate without pushing a button. (Z-0484-2008) |
| Stryker | Disposable ***StrykeProbe*** | II | Tips have electrodes that are too large to fit monopolar cables. (Z-0573/0574-200) |
| Stryker | ***Reflex*** Revision Screwdriver | II | The inner shaft does not extend far enough from the tip of the screwdriver to fully engage the bone screw. (Z-2238-2008) |
| Stryker | Ray TFC Device with End Caps | II | The label is incorrect. It reads "20 mm x 26 mm" instead of "20 mm x 21 mm." (Z-0151-2009) |
| Stryker | ***Reflex*** Hybrid Variable Self-Tapping Bone Screw | III | Screw was anodized with the incorrect color. (Z-0217-2009) |
| Stryker | ***Radius*** Rod Persuader and Radius Capsin | II | The T-bar of the persuader froze due to a loosening screw causing the device to fail, and the capsin has a separation of the tip from the inserter. (Z-1377/1378-2008) |
| Stryker | Short-Barrel Sideplate | II | May contain a five-hole slot. (Z-1865-2008) |
| Stryker | Osteosynthesis Reduction Spoon | II | There is a potential for breakage. (Z-0191-2009) |
| Stryker | UHR Universal Bipolar Component | II | The device may have an incorrect locking ring assembled with the UHR bipolar head. (Z-0621/0656-2008) |
| Stryker | ***Triathlon*** Femoral Sizer | II | When attempting to position sizer, the pre-setting may slip from "L" (left knee) to "R" (right knee), and vice versa. (Z-1864-2008) |
| Sun Biomedical Labs | Various ***VisuaLine*** Devices | II | Product was sold while the devices were under FDA 510(k) review, which was subsequently denied. (Z-1873/1875-2008) |
| Sunquest Information Systems | Laboratory Information System | II | The test results of one patient may be filed to another patient when the order codes are the same. (Z-0207-2009) |
| Sunquest Information Systems | Laboratory Software | II | There have been instances in which an error that occurred at the database level or originated in the operating system was not communicated or displayed in the "Graphic User Interface" application, so the activity continued. (Z-0214-2009) |
| Sun Med | ***GreenLine/D*** Laryngoscope Blades | I | A breakage problem of the acrylic bundles at both distal and proximal ends of the light tube has been detected. (Z-0459-2009) |
| Sunrise Medical | ***Quickie*** Rhythm Power Wheelchair | II | Product experiences a longer-than-expected stopping distance, which may cause injury to the user. (Z-1531/1532-2008) |
| Sunrise Medical | ***Quickie Groove*** Power Wheelchair | II | Rear bolts holding the frame in place may shear and the front bolts may potentially come off the posts, resulting in partial- or full-seat detachment in a sudden stop or crash. (Z-2339-2008) |

| Manufacturer | Product | Class | Reason |
|---|---|---|---|
| Superior Products | ***OxyServe II*** Oxygen Conserving Regulator | II | Device was leaking oxygen. (Z-0529-2008) |
| Surgical Specialties | Black Mono Nylon Suture | III | Boxes labeled as "3-0 black mono nylon" contains 4-0 black-braided silk suture. (Z-0034-2009) |
| Synthes | Power Drive | II | The product is mislabeled. (Z-2395-2008) |
| Taiwan An I | Bariatric Wheelchair | II | There is a potential for users to pinch their fingers between the seat bars when opening the wheelchairs. (Z-1770/1772-2008) |
| Teleflex Medical | Hudson RCI | II | There is a decrease in flow output through the nebulizer. (Z-0211-2008) |
| Teleflex Medical | Various ***Weck*** Clips | II | A hole in the sterile unit blister pack was detected that would compromise sterility. (Z-0156/0160-2009.) |
| Tenet Medical Engineering | Wrist Stabilization Kit | II | Sterility seals on some of the firm's wrist stabilization kit pouches may be compromised. (Z-0577/0579-2008) |
| Terumo Cardiovascular Systems | Ultrasonic Air Sensors | II | The air sensor may malfunction and trigger false alarms, and may continue to alarm, thus preventing the device from being reset. (Z-0530/0532-2008) |
| Terumo Cardiovascular Systems | Cardiovascular Procedure Kit | II | Loose flash at tip of weighted flexible sucker. (Z-1311/1313-2008) |
| Terumo Cardiovascular Systems | ***Advanced*** Perfusion System 1 Base | II | The units may exhibit blank or distorted displays, loss of local control and/or may have local control knobs that are difficult to use. (Z-0203/0204-2009) |
| Terumo Cardiovascular Systems | ***Sarns*** Level ***Sensor II*** Alert Level Sensor Transducer | II | The level sensor may not properly couple to the reservoir, resulting in a "sensor not attached" message, an alert or alarm condition, or a failure to detect a low-level condition. (Z-0295/0296-2009) |
| Terumo Cardiovascular Systems | ***Advanced*** Perfusion System 1 | II | The pumps may fail to power up or experience unplanned pump stops. (Z-0309/0310-2009) |
| Terumo Cardiovascular Systems | ***Sarns*** Sternal ***Saw II*** System Power Unit | II | The drive power cable cannot be fully inserted into the power unit or can only be inserted with difficulty, resulting in the device not being operational. (Z-0358/0359-2009) |
| Terumo Cardiovascular Systems | ***Sarns*** Level ***Sensor II*** Pads | II | The level sensor holder may detach from the adhesive pad, causing the sensor to lose contact with the venous reservoir, which may result in a detached sensor indication or false alarm. (Z-0311-2009) |
| Terumo Cardiovascular Systems | ***Advanced*** Perfusion System 1 | II | Overspeed and underspeed errors, erratic pump behavior, jerky operation at low RPMs, pump instability, pump slowdowns and pump stops due to overspeed max events may occur due to a grease leak onto the motor speed encoder disk. (Z-0354/0357-2009) |
| Terumo Cardiovascular Systems | ***Advanced*** Perfusion System 1 | II | The power supply may fail to charge the batteries due to various hardware malfunctions. (Z-0445/0446-2009) |

| Manufacturer | Product | Class | Reason |
|---|---|---|---|
| Therics | ***FormPutty*** Bone Void Filler | III | The patient label inside the package has an incorrect expiration date. (Z-2375-2008) |
| ThermoFisher Scientific | Buffered Formalin Phosphate | II | Assay tests on retention sample of 10% Buffered Formalin Phosphate showed it to be 3.417%, which is below the specification of 4-5%. (Z-2159-2008) |
| Thomas Medical Products | XTW Needles | II | Difficulty inserting guide wire through introducer needle. (Z-0131-2009) |
| Thomas Medical Products | Split Sheath with Valve and Sideport | II | Failure to insert the guide wire through the introducer needle. (Z-0280-2009) |
| Thomas Medical Products | ***BardSelect*** Percutaneous Catheter Introducer Sets | II | Failure to insert the guide wire through the introducer needle. (Z-0441/0444-2009) |
| Thoratec | ***HeartMate II*** Left Ventricular Assist System | II | Over time, wear and fatigue of the percutaneous lead connecting the pump with the external system controller may result in damage that has the potential to interrupt pump function and may require a re-operation to replace the pump. (Z-0496-2009) |
| Thortex | Metal Hemiarthroplasty | II | Labeling presented conflicting information as to whether the device was sterile or not. (Z-2228-2008) |
| Tomo Therapy | ***Hi-Art*** System | II | The registration adjustment field numbers may appear as nonsense characters or values on printed pages of the register tab. (Z-1615-2008) |
| Toshiba | ***Aquilion*** Systems | II | Intermittent shifting of CT numbers causes the actual dose to the patient to be greater than expected, when "Sure Exposure "option is used. (Z-1707/1708-2008) |
| Toshiba | ***Aplio XG*** Diagnostic Ultrasound System | II | When using dynamic image acquisition modes the panel may lock up if the operator attempts to perform a still-image capture. (Z-0305-2008) |
| Tri-State Hospital Supply | ***Centurion*** Healthcare Products Laceration Tray | III | Some of the kits contain a 1-inch 21G needle instead of the 1- to 1/2-inch 21G needle specified on the kit label. (Z-0729/0730-2008) |
| Unimax Medical Systems | ***Genicon*** Pyramidal Trocar | II | The stainless steel tips exhibited contamination that resembled rust, and there also was pitting on the tip of the trocar. (Z-0622-2009) |
| Utah Medical Products | ***Intran Plus*** Disposable Intrauterine Pressure Catheter System | II | Possibility of compromised package sterility prior to the expiration date. (Z-2200-2008) |
| VTech Com-munications | ***ProTime*** Microcoagulation System Instrument | II | An increase in the frequency of nonconformance reports for certain displayed error messages. (Z-0546/0548-2008) |
| Varian Medical Systems | ***Eclipse*** Treatment Planning System | II | A software error causes the wedge accessory calculation to be ignored in the radiotherapy treatment plan. (Z-1612-2008) |
| Varian Medical Systems | Real-Time Position Management System | II | Software failure can occur that affects the gated radiotherapy treatment when phase-based gating is used. (Z-0554-2008) |

| Manufacturer | Product | Class | Reason |
|---|---|---|---|
| Varian Medical Systems Inc. | Clinac Accelerator | II | The collimator drive chain may break or slip off of its drive track, allowing the collimator to rotate freely without motor control. (Z-0544/0545-2008) |
| Varian Medical Systems | ***VARiS*** | II | The ARC treatment plans containing a "Dose Dynamic MLC" for IMRT delivery will not be recognized properly by the system. (Z-0720-2008) |
| Varian Medical Systems | High-Definition 120 ***MultiLeaf*** Collimator | II | Software anomaly may result in failure of an MLC leaf to reach planned position, potentially resulting in misadministration of dose to a patient. (Z-1459-2008) |
| Varian Medical Systems | On-Board Imager | II | If used with a third-party radiation therapy treatment planning software system, mistreatment may occur because of a misalignment. (Z-1442-2008) |
| Varian Medical Systems | ***FastPlan*** | II | Due to issues with image-orientation verification, a patient may receive all or some of prescribed high dose to healthy tissue instead of intended area. (Z-2195-2008) |
| Varian Medical Systems | ***Eclipse*** | II | Software anomaly in which swapping IDs of planning fields can produce inconsistencies between dose matrix and field parameters. (Z-2308-2008) |
| Varian Medical Systems | ***Exact*** Couch | II | During couch movement, a patient's fingers may get pinched at certain points which could result in broken, disengaged or pinched fingers. (Z-0117-2009) |
| Varian Medical Systems | RV Software | II | A software malfunction might result in a misadministration. (Z-0164-2009) |
| Varian Medical Systems | ***Acuity*** with Conebeam Computed Tomography | II | The image orientation tag may not be set correctly if the patient has been scanned with an orientation other than Head First Spine. (Z-1460-2008) |
| Varian Medical Systems | ***VariSource*** CT/MR Ring & Tandem Applicator Set | II | Device may exhibit inaccurate positioning and lead to unintended dose delivery during brachytherapy treatment. (Z-2081-2008) |
| Varian Medical Systems | ***Varis Aria*** Radiation Oncology | II | Dose delivery may be altered after import from a third-party planning system during radiation therapy. (Z-2194-2008) |
| Venice International | Various Devices | II | Firm cannot validate the sterilization process for a variety of products. (Z-1661/1683-2008) |
| Ventana Medical Systems | ***Symphony*** Staining System | II | A shock hazard exists. (Z-0300-2008) |
| Ventana Medical Systems | Various ***Benchmark*** and ***Discovery*** Slide Staining Systems | II | The staining platform includes one or more carboys that may have the potential to leak if the spigot is either improperly installed or not fully closed. (Z-0537/0541-2008) |
| Ventana Medical Systems | ***Symphony*** Staining System | III | The T-fitting needs to be larger to securely hold the tubing in place to eliminate any possible fluid leak due to the tubing movement. (Z-0553-2008) |
| Ventlab | Latex-Free Breathing Bags | II | The breathing bag may separate from the bushing during use. (Z-1162/1164-2008) |

| Manufacturer | Product | Class | Reason |
|---|---|---|---|
| Via Biomedical | ***Centros*** Chronic Hemodialysis Curved Catheter Sets | II | The cuff may be inadequately attached to the catheter, resulting in possible catheter movement or leakage at the insertion site. (Z-2396/2398-2008) |
| Viasys | ***Corflo*** Anti-I.V. NG Tube | III | The male luer adapter may be the wrong component; therefore, the feeding set would not be able to be connected to the tube, nor would the cap fit securely. (Z-2306-2008) |
| Viasys | ***Avea*** Ventilator | II | There is a potential of alarms not being activated subsequent to specific electronic faults that may cause INOP condition. (Z-0982/0986-2008) |
| Vibe Technologies | ***Vibe*** Machine | I | Device was marketed without FDA approval for claims that it cures cancer, infections and depression. (Z-0201-2009) |
| Visx | Advanced Medical Optics ***WaveScan WaveFront*** System | II | Two software-caused errors result in an erroneous treatment calculation in patients. (Z-0365-2008) |
| Visx | Opthalmic Microsurgical System | II | The physician may be unable to make a cut during cataract surgery. (Z-1702-2008) |
| Visx | ***Excimer*** Laser System | II | There was a significant overcorrection in one eye of a patient who had received a ***WaveFront***-guided ***Lasik*** treatment. (Z-1695-2008) |
| Visx | ***Star Excimer*** Laser System | II | The chair moved while in the patient-loading position under an ***IntraLase FS*** laser. (Z-1139-2008) |
| Vital Images | ***ViTALConnect*** | II | The problem arises when a user draws a selected region of interest in order to calculate the SUV statistics of the region. If the user then changes the slice shown by scrolling through additional slices, the original SUV measurements will remain on the screen and do not update with new values for the current slice. (Z-0520-2008) |
| Vital Signs | Light Wand Orotracheal Lighted Stylet; Vital Signs Intubation Pack; Light Wand Intro Pack | II | Light protector may detach from lighted stylet during intubation. (Z-2454/2456-2008) |
| Vitrex Medical | Blood Gas Capillary Tubes | II | Tubes contained contaminated lithium heparin. (Z-2152-2008) |
| VNUS Medical Technologies | ***ClosureFast*** Catheters | II | Instructions for use have been changed to include a modified placement recommendation. (Z-0542/0543-2008) |
| Wampole Labs | ***Clinitest*** hCG Cassette Pregnancy Test | II | False-negative hCG results due to decreased sensitivity. (Z-1715-2008) |
| Warsaw Orthopedic | Sofamor Danek Colorado Spinal System Break-Off Nut | II | Two thread grooves are missing on the nut, which may cause damage to the bone screw and result in the need for the bone screw to be replaced. (Z-0125-2008) |
| Warsaw Orthopedic | CD ***Horizon*** Spinal System Agile Dynamic Stabilization Device | II | Shear failure of the cable component of the system. (Z-1408/1441-2008) |

| Manufacturer | Product | Class | Reason |
|---|---|---|---|
| Wescor | ***Osmocoll***; Colloid Osmotic Pressure Calibrator/Osmolality Control; Colloid Osmotic Pressure Control Reference | III | The control does not provide an accurate calibration value/readings when performing Colloid Osmotic Pressure testing. (Z-1350/1351-2008) |
| Wightman Engineering Services | ***da Vinci S*** Instrument Cannula with Outlet | II | Incorrect dimension on luer on smoke evacuation cannula not allowing for secure attachment function. Also, the external labeling lot number differs from the lot number etched on the cannula. (Z-1348-2008) |
| Winer Industries | ***Exu-Dry*** Wound Burn Dressing | II | Package integrity was compromised. (Z-1199/1217-2008) |
| Wipro GE Medical Systems | ***Logiq 3*** Expert Ultrasound Scanner | II | An attempt by the user to activate biopsy guidelines while this probe is in use will cause incorrect guidelines to be displayed on the image. (Z-1155-2008) |
| Xoran Technologies | ***MiniCAT*** System | III | The devices do not bear the manufacturer's name or address. (Z-0826-2008) |
| Zest Anchors | Locator Abutment for 5.7 Screw-Vent & Compatibles | III | The locator abutments for the 5.7 screw-vent and compatibles do not fit properly in all sizes of the Zimmer Dental 5.7mm-diameter tapered screw-vent implants. (Z-0298-2009) |
| Zimmer | Metasul Head | III | The wrong part may be in the package. (Z-2299-2008) |
| Zimmer | Durom Cup | II | Instructions for use/surgical technique instructions are inadequate. (Z-2415/2426-2008) |
| Zimmer | ***Nexgen Complete*** Knee Solution Articular Surface Insertion Instrument | II | The instrument is prone to fracture during use. (Z-1863-2008) |
| Zimmer | M/G Unicompartmental Knee System | III | An impurity in the metal may affect the strength of the screw, resulting in breakage and/or surgical delays. (Z-2300-2008) |
| Zimmer | Arnot-Ogden Med Ctr Hip Pack | II | A component of the convenience kit was not sterilized. (Z-1808/1809-2008) |
| Zimmer | ***Nexgen Complete*** Knee Solution MIS Total Knee Procedure Tibial Broach Impactor | II | The instrument may fracture during use, resulting in metal fragments being left in the patient post-surgery, which could cause implant failure. (Z-2301-2008) |
| Zimmer | ***Alumina*** Ceramic Femoral Head | II | When used with cobalt/chromium hip stems, the average test values for ceramic head bursting falls below the guidance document limits if the taper is made by casting instead of by forging. (Z-0299/0304-2009) |
| Zimmer | ***Trilogy*** Acetabular System Shell with Cluster Holes | II | The units may not contain the locking ring or the etched alignment marks on the rim. (Z-0620-2008) |
| Zimmer | Compression Plate-Broad | II | An impurity in the metal may affect the strength of the plate or biocompatibility of the material with the body. (Z-2179-2008) |

| Manufacturer | Product | Class | Reason |
|---|---|---|---|
| Zimmer | Various Pulsavac Kits | II | The effect of a silicone stain produced during assembly operations on the sterility barrier properties of the Tyvek lids was not been validated by the firm. (Z-0856/0865-2008) |
| Zimmer | ***Miller*** Bone Cement Injector Front Loading Cartridge Kit | II | The cartridge is brittle and at increased risk of breakage. (Z-2295-2008) |
| Zimmer | Various ***Patient Helper*** Reinforced Overhead Bars | II | If the bed is in the upright position and the bar is dropped rapidly or in free-fall, it could strike the patient in the bed, and the drop could present a laceration hazard by creating a sharp edge on the metal bar. (Z-2296/2298-2008) |
| Zimmer | ***Hemovac*** Wound Drainage Device Infection Control Kits | II | The kits may disassemble at the fluid collection port, which would present a risk of exposure to blood borne pathogens to health care providers should it occur during use. (Z-1448/1458-2008) |
| Zimmer | ***Dermacarriers II*** Skin Graft Carriers | II | Lack of assurance of sterility, as the packages may not have been sealed. (Z-1550/1555-2008) |
| Zimmer | Various Wound Drainage Devices | II | The sterility of the device may be compromised due to the possible presence of slits or pinholes in the packaging. (Z-1480/1509-2008) |
| Zimmer | ***Cyclone*** Anterior Cervical Plates | II | The screw-locking cap may fracture when the surgeon rotates it into the locked position. (Z-1717/1748-2008) |
| Zoll Medical | ***E Series*** Defibrillator | II | Patient records that have been stored, then later transmitted or printed, may not be the correct record. (Z-1167-2008) |

# FDA Warning Letters

***The following chart lists medical device-related warning letters released by FDA from Jan. 13 through Feb. 3. If an inspection led to the warning letter, the location of the inspected facility and dates of inspection are noted; otherwise, the location of the warning letter recipient is listed.***

| Description | Summary |
|---|---|
| **Hammill Manufacturing Co.**<br>Warning letter date: Jan. 6, 2009<br>Location: Maumee, Ohio<br>Inspection dates: Sept. 4-Nov. 10, 2008 | QS reg violations identified at manufacturer of implantable prosthetics. The firm failed to analyze and trend sources of quality data, and the company's corrective and preventive action procedure didn't describe the types of quality data that should be trended. Nonconforming product wasn't evaluated and investigated; for example, 43 in-process failure investigations weren't documented. Complaints weren't evaluated and investigated; for example, there were no documented failure investigations for to 13 complaints. CAPA activities weren't documented, and corrective actions weren't verified and/or validated. The firm also failed to establish and maintain an adequate organizational structure; for example, the company's quality manager lacked the time and resources to complete quality system requirements. Process validation activities weren't conducted, and device master records weren't maintained. The company didn't establish process control procedures for the laser-etching process used to label devices. In-process and final inspection forms, as well as work instructions, weren't reviewed and approved. Document change records weren't maintained, and quality audits didn't ensure that the firm's quality system was in compliance. Finally, top management didn't participate in management reviews. The manufacturer's response to the FDA-483 was deemed somewhat inadequate. [Issued by Cincinnati District Office] |

| Description | Summary |
|---|---|
| **I-Flow Corp.**<br>Warning letter date: Dec. 22, 2008<br>Location: Lake Forest, Calif.<br>Inspection dates: March 11-May 12, 2008 | Manufacturer of elastromeric infusion pumps cited for QS and MDR reg violations. The company failed to maintain design verification procedures; for example, devices weren't tested for labeled design specifications during design output activities. Design change procedures also weren't established and maintained. Process validation activities weren't conducted; for example, the device's pre-sterilization and post-sterilization flow-rate specifications were different. Further, validation reports didn't identify device storage conditions, study start and end dates, monitoring data, or the equipment used for the testing. The firm failed to evaluate whether there was a need for revalidation when the device failed to meet acceptance criteria. Actions weren't identified to correct and prevent the recurrence of nonconforming product; for example, corrective actions didn't address identified root causes of device problems. Corrective and preventive actions weren't verified or validated. In addition, the company failed to establish and maintain procedures for evaluating complaints; for example, post-market surveillance reviews weren't performed. The firm didn't investigate the root cause of device malfunctions, and failed to record and investigate the nature of complaints; for example, a form used to document complaints didn't require details of the complaint, such as the relationship of the device to the patient, the event description, and other details. Procedures weren't followed when changes were made to the device. Rework procedures weren't established and maintained; for example, rework didn't include retesting and reevaluation to ensure that the reworked product met specifications. Further, procedures weren't established and maintained to ensure that requirements for in-process product were met. Acceptance procedures also weren't established and maintained. The company didn't evaluate and select suppliers based on their ability to meet specified requirements; for example, supplier audits weren't conducted. Supplier records weren't established and maintained, and device history records weren't maintained. Finally, the firm failed to inform FDA of an MDR-reportable event in a timely fashion. The manufacturer's response to the FDA-483 was deemed mostly inadequate. [Issued by Los Angeles District Office] |
| **Nebion LLC**<br>Warning letter date: Nov. 17, 2008<br>Location: Los Angeles<br>Inspection dates: June 11, 12 & 17, 2008 | Manufacturer cited for QS, MDR and pre-market reg violations. The firm failed to establish and maintain design control procedures; for example, a design and development plan, design input and output procedures, design review procedures, design verification and validation procedures, and design transfer procedures weren't established. Procedures also weren't established to ensure that the device conformed to specifications. The company didn't establish and maintain procedures for acceptance activities or corrective and preventive actions; for example, controls weren't established to capture complaints or product problems. Complaint file procedures weren't established. Further, the firm didn't establish procedures to ensure that supplied products met specified requirements. Management review procedures weren't established. Device master records and device history records weren't maintained. In addition, document control procedures weren't established and maintained, and the firm failed to establish procedures that identified components, raw materials, subassemblies and finished devices. A quality policy and quality plan were not established. MDR procedures weren't established and maintained. Finally, the firm was selling its device without pre-market approval or pre-market clearance from FDA. The manufacturer's response to the FDA-483 was deemed inadequate. [Issued by Los Angeles District Office] |

# In Brief

**GHTF supplier control guidance released:** The Global Harmonization Task Force (GHTF) released a new guidance Feb. 5 designed to help manufacturers do a better job with the often fraught task of ensuring supplier quality. "Quality Management System – Medical Devices – Guidance on the Control of Products and Services Obtained From Suppliers" advises companies to control and audit "sub-tier" suppliers when necessary, noting that firms may need to "extend control beyond the first-tier supplier due to the effects changes made by a second- or third-tier supplier may have on the supplied product/part or the medical device." The document also instructs companies to consider various risks – such as the complexity and criticality of supplied components – when selecting a vendor. Further, "information about potential suppliers (such as technical, financial, continuity of supply, etc.) should be used to determine additional potential risks." FDA GMP/quality systems expert Kim Trautman says FDA intends eventually to adopt the GHTF document as an agency guidance to help industry better carry out Quality System Regulation requirements related to supplier control ("The Silver Sheet" May 2008). The GHTF document can be found at www.ghtf.org/documents/sg3/sg3final-N17.pdf.

**GAO deems FDA oversight of devices, drugs as 'high-risk':** The Government Accountability Office (GAO) added enhanced oversight of devices, drugs and other medical products to its list of "high-risk" priorities in a Jan. 22 report to Congress. Specifically, the document cites deficiencies in foreign manufacturing inspections, post-market monitoring, and oversight of promotional materials and clinical trials related to medical products. "Many have begun expressing concern about FDA's ongoing ability to fulfill its mission of ensuring the safety and efficacy of drugs, biologics and medical devices," the GAO report states. FDA oversight of foreign manufacturers is plagued by inconsistent foreign establishment databases, difficulties scheduling and conducting foreign inspections, and other hurdles, the report notes. The U.S. Department of Health and Human Services has agreed that FDA should conduct more foreign inspections, but has not provided a timetable for accomplishing that goal. GAO has released a list of government operations that it considers high risk about every two years since 1990, usually prior to the start of a new Congress.

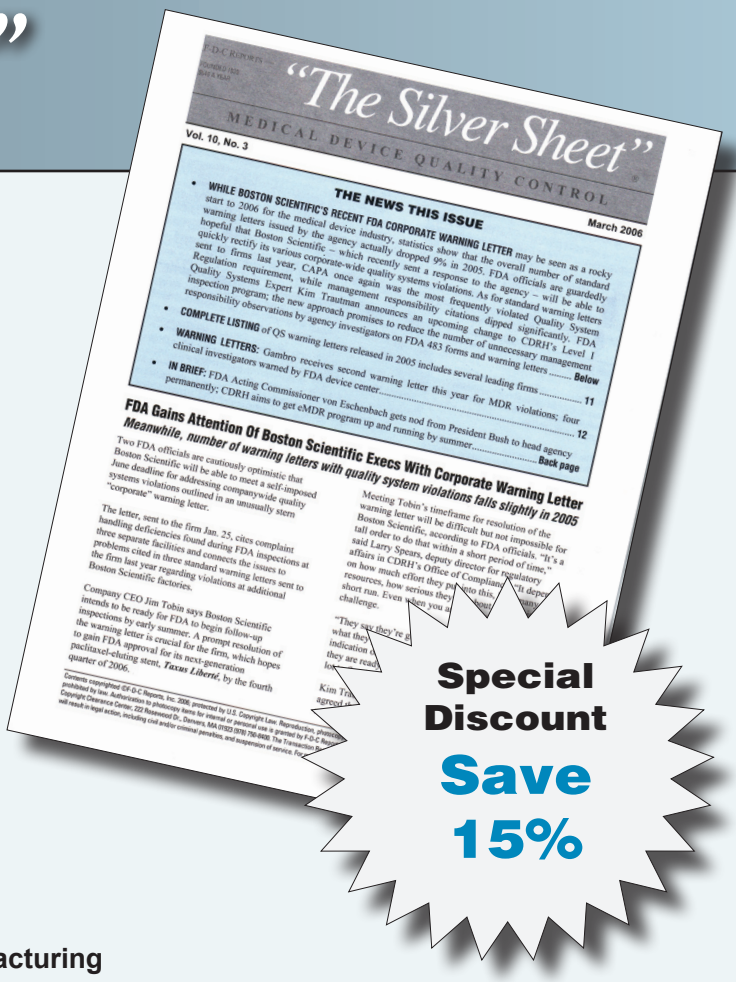
**Rule for unique device identifiers likely ready by end of year:** CDRH expects a proposed rule to implement a system of unique device identification (UDI) to be ready by year-end. Although the use of a UDI system that would label devices with a barcode-type identifier to track individual products has been discussed for years, the initiative got a boost in late 2007 when it was mandated by the FDA Amendments Act ("The Silver Sheet" November 2007). The act gives the agency the opportunity to identify exceptions for certain products. Establishing those exceptions is one of the primary challenges center staffers are wrestling with in crafting the rule, says Jay Crowley, CDRH senior advisor for patient safety. "Putting a UDI on everything within a [hospital supplies] kit, or every syringe, for example, might be very difficult, cost-prohibitive," and not particularly useful for the end-user, he says.

**Scientific versus clinical judgment at CDRH:** The former director of FDA's Office of Science and Engineering Laboratories (OSEL) says he is disappointed by recent claims levied by a group of CDRH scientists that center leadership ordered or pressured staff reviewers to modify scientific evaluations, conclusions and recommendations, among other charges ("The Silver Sheet" January 2008). Larry Kessler, who spent 13 years with CDRH before joining the University of Washington's School of Public Health on Jan. 2, says he does not believe "that the basic thrust of those complaints is justified or warranted." However, the complaints do highlight a dichotomy within the center between scientifically and clinically based decisions, he says. "I do believe that [CDRH's] decision-making doesn't use scientific principles and practices enough. I think it sometimes relies on clinical judgment," Kessler says, pointing out that clinicians often pose problems for FDA. "Clinicians see clinical problems they would like to solve and, despite the lack of scientific evidence, hope that the product will work. And sometimes they feel that's sufficient justification to put something on the market," he says. "As a scientist, I disagree."

**Establishment registration lapse:** FDA is reminding device firms to meet fiscal year 2009 establishment registration and listing requirements to avoid an extra registration fee increase of up to 8.5 percent (on top of the regular annual 8.5 percent increase) in 2010. As of the Jan. 1 deadline, 97 percent, or nearly 12,442 establishments, had paid the fee, but only 10,848 had actually registered and listed. By statute, FDA must further raise the registration fee for 2010 if fewer than 12,250 firms register. The base registration fee for FY 2010 is $2,008; the maximum adjustment would add $171 to the FY 2010 fee.

# "The Silver Sheet"

## Medical Device Quality Control

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